

Clinical Policy: Lidocaine-Prilocaine (EMLA)

Reference Number: OR.CP.PMN.1004

Effective Date: 10.01.21

Last Review Date: 09.24

Line of Business: Medicaid – Trillium Oregon Health Plan

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Lidocaine-prilocaine (EMLA) is a combination of two amide local anesthetics available as a topical cream.

FDA Approved Indication(s)

EMLA is indicated for:

- Topical local anesthetic to the skin
- Topical anesthetic to genital mucous membranes

Covered Alternatives:

- Covered topical analgesics include:
 - Lidocaine 4% cream
 - Lidocaine 2% gel and viscous solution
 - Capsaicin 0.025%, 0.075% and 0.1% cream
- Current Trillium Preferred Drug List listed at:
 - <https://www.trilliumohp.com/providers/pharmacy.html>

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Trillium Community Health Plan that lidocaine-prilocaine is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Local analgesia of skin (must meet all):

1. Member has an implantable port in place;
2. Lidocaine-prilocaine cream is to be used prior to needle insertion into port;

Approval duration: up to 1 year

B. Local analgesia of genital mucosa (must meet all):

1. Member has diagnosis of vulvar dysplasia;
2. Lidocaine-prilocaine cream is to be used prior to local anesthetic for before surgical procedure(s);

Approval duration: up to 1 year

C. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the PDL the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the PDL the non-formulary policy for the relevant line of business: OR.CP.PMN.1001 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);

Approval duration: up to 1 year

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the PDL the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the PDL the non-formulary policy for the relevant line of business: OR.CP.PMN.1001 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. References

1. National Library of Medicine (U.S.). (2019, April 1). Label: Lidocaine and Prilocaine Cream. In *DailyMed*. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=b6c88c84-cd82-4390-aea5-b04f15f57143>
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2022. Available at: <https://www.clinicalkey.com/pharmacology/>
3. DRUGDEX[®] System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed June 28, 2024.

Reviews, Revisions, and Approvals	Date	Plan Approval Date
Policy created: adapted from previously approved policy TCHP.PHAR.1808 Lidocaine-Prilocaine (EMLA)	06.15.21	07.15.21
3Q 2022 annual review: no significant changes; references reviewed and updated	06.15.22	07.07.22
3Q 2023 annual review: no significant changes; template changes applied to other diagnoses/indications and continued therapy section; references reviewed and updated.	06.15.23	09.19.23
3Q 2024 annual review: no significant changes; references reviewed and updated.	06.28.24	09.17.24

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise

professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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