Topical Anesthetics

Policy # 00580
Original Effective Date: 01/01/2018
Current Effective Date: 10/14/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider generic lidocaine ointment and generic lidocaine/prilocaine cream to be **eligible for coverage**** when the patient selection criteria are met for the requested drug.

Patient Selection Criteria

Coverage eligibility will be considered for generic lidocaine ointment or generic lidocaine/prilocaine cream when the following criteria are met for the requested drug:

- The requested drug is generic lidocaine ointment:
    - Patient is using as an anesthetic lubricant for intubation; AND has tried and failed (e.g. intolerance or inadequate response) generic lidocaine 2% jelly (unless there is clinical evidence or patient history that suggests the use of the alternative product will be ineffective or cause an adverse reaction to the patient); OR
    - Patient is using for production of anesthesia of accessible mucous membranes of the oropharynx AND has tried and failed (e.g. intolerance or inadequate response) ALL of the following (unless there is clinical evidence or patient history that suggests the use of the alternative products will be ineffective or cause an adverse reaction to the patient):
        - Over the counter benzocaine 10% or 20% gel, liquid, ointment, or spray; AND
        - Generic lidocaine 2% jelly; AND
        - Generic lidocaine 4% solution; OR

- Patient is using for temporary relief of pain associated with minor burns (including sunburn), temporary relief of pain associated with abrasions of the skin, or temporary relief of pain associated with insect bites AND has tried and failed (e.g. intolerance or inadequate response) ALL of the following (unless there is clinical evidence or patient history that suggests the use of the alternative products will be ineffective or cause an adverse reaction to the patient):
  - Over the counter benzocaine 10% or 20% gel, liquid, ointment, or spray; AND
  - Over the counter dibucaine 1% ointment; AND
  - Generic lidocaine 2% jelly; AND
  - Generic lidocaine 4% solution.

  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

- The requested drug is generic lidocaine/prilocaine cream:
  - Patient is using for topical anesthesia of normal intact skin for local analgesia [e.g. temporary relief of pain associated with minor burns (including sunburn), temporary relief of pain associated with abrasions of the skin, or temporary relief of pain associated with insect bites] AND has tried and failed (e.g. intolerance or inadequate response) ALL of the following:
    - Over the counter benzocaine 10% or 20% gel, liquid, ointment, or spray; AND
    - Over the counter dibucaine 1% ointment; AND
    - Generic lidocaine 2% jelly; AND
    - Generic lidocaine 4% solution; OR

    *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
  - Patient is using for topical anesthesia of genital mucous membranes for superficial minor surgery OR using for topical anesthesia of genital mucous membranes as pretreatment for infiltration anesthesia; OR
  - Requested product is used for topical anesthesia of normal intact skin for local anesthesia prior to procedures (e.g. IV cannulation, venipuncture, skin graft harvesting, needle insertion, etc).

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of generic lidocaine ointment or generic lidocaine/prilocaine cream when the required alternative products are not tried and failed (unless there is clinical evidence or patient history that suggests the use of the alternative products will be ineffective or cause an adverse reaction to the patient) to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of generic lidocaine ointment or generic lidocaine/prilocaine cream for indications other than those listed in the policy for the requested drug to be **investigational.***

Background/Overview

Generic lidocaine/prilocaine cream, formerly available as brand Emla®‡, is an emulsion containing a eutectic mixture of lidocaine and prilocaine. It works to provide dermal analgesia by the release of lidocaine and prilocaine from the cream into the epidermal and dermal layers of the skin and by the accumulation of lidocaine and prilocaine near the dermal pain receptors and nerve endings. It is indicated as a topical anesthetic for use on normal intact skin for local anesthesia and for genital mucosal membranes for superficial minor surgery and as pretreatment for infiltration anesthesia of genital mucosal membranes. Lidocaine ointment is indicated for the production of anesthesia of accessible mucous membranes of the oropharynx, however there are other acceptable uses for this product as mentioned in the package insert (minor burns, abrasions of the skin, insect bites, etc). There are various alternatives in this class of medications that are more cost effective (and equally effective) options (depending on the intended use of the requested product). These include: generic lidocaine 2% jelly, over the counter benzocaine products (gel, liquid, ointment, spray), generic lidocaine 4% solution, and over the counter dibucaine.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Lidocaine/prilocaine cream is indicated as a topical anesthetic for use on normal intact skin for local anesthesia and for genital mucosal membranes for superficial minor surgery and as pretreatment for infiltration anesthesia of genital mucosal membranes. Lidocaine ointment is indicated for the production of anesthesia of accessible mucous membranes of the oropharynx.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy take into consideration clinical evidence or patient history that suggests all over the counter or generic alternatives to generic lidocaine ointment or generic lidocaine/prilocaine cream will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using generic lidocaine ointment or generic lidocaine/prilocaine cream over the available generic alternatives. The purpose of this policy is to assure that these products are being used appropriately and that the most cost effective (and equally efficacious) products are tried and failed prior to utilization of the requested product.

References

1. Emla [package insert]. Actavis Pharma Inc. Parsippany, NJ. 2018.
2. Lidocaine ointment [package insert]. E. Fougera & Co. Melville, New York. Updated October 2001.

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Policy History

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09/07/2017	Medical Policy Committee review
09/20/2017	Medical Policy Implementation Committee approval. New policy.
09/06/2018	Medical Policy Committee review
09/19/2018	Medical Policy Implementation Committee approval. No change to coverage.
09/05/2019	Medical Policy Committee review
09/11/2019	Medical Policy Implementation Committee approval. No change to coverage.
09/03/2020	Medical Policy Committee review
09/09/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/02/2021	Medical Policy Committee review
09/08/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/01/2022	Medical Policy Committee review
09/14/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/07/2023	Medical Policy Committee review
09/13/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2024	Medical Policy Committee review
09/11/2024	Medical Policy Implementation Committee approval. Removed brand Emla from the policy as it is no longer manufactured.

Next Scheduled Review Date: 09/2025

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.