LIDOCAINE external ointment USP, 5%

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Lidocaine 5% ointment is indicated for the production of anesthesia of accessible mucous membranes of the oropharynx; and is indicated as an anesthetic lubricant for intubation; and is indicated for the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites.

Lidocaine is a local anesthetic of the amide type. Lidocaine stabilizes neuronal membranes by inhibiting ionic changes that are required for the initiation and conduction of impulses from sensory nerves.

Lidocaine is available in numerous dosage forms in varying percentages that are available over-the-counter and as prescription products. Lidocaine 2% jelly and 5% ointment are used as an anesthetic lubricant for intubation, a 2% topical viscous solution, 4% topical solution, and 5% ointment are used as an oropharynx anesthetic, and a variety of strengths, 2-5%, in gel, spray, cream, lotion, or ointment are used for skin discomfort, irritation, itching, or pain. Lidocaine 5% cream or gel are used for anorectal discomfort and lidocaine jelly is used for urethral pain.
LIDOCAINE external ointment USP, 5% (cont.)

In addition, other local anesthetic agents (benzocaine, dibucaine, and pramoxine) can be used for pain and itching caused by sunburn, minor burns, minor cuts, scrapes, insect bites or minor skin irritation.

Definitions:

Oropharynx is subdivided into five areas: these include lateral pharyngeal walls, tonsillar regions, posterior wall, base of tongue, and soft palate

Drug related events:

Ineffective / failure

Use of a drug employing optimal doses (FDA-recommended doses) for optimal duration; where the condition being treated has not improved or worsened

A request for branded agent due to generic drug failure or ineffectiveness will be assessed for potential approval with documentation of use of optimal dose / duration of the generic product and meeting other criteria within the coverage guideline. When the drug in question is a combination product, there must be documentation of failure / ineffectiveness of concurrent use (each ingredient used at the same time) of individual generic components. When the drug in question is a low dose formulation, there must be documentation of failure / ineffectiveness of low dose generic formulation.

Adverse Drug Event: Allergic reaction / Hypersensitivity / Intolerance

Use of a drug produced a significant reaction where continued use of the drug places the individual at risk for either lack of improvement or worsening of the condition being treated or at risk for harm and the concern is documented in medical record. A significant adverse drug event is when an individual's outcome is death, life-threatening, hospitalization (initial or prolonged), disability resulting in a significant, persistent, or permanent change, impairment, damage or disruption in the individuals' body function/structure, physical activities or quality of life, or requires intervention to prevent permanent impairment or damage.

Allergic reaction / hypersensitivity – may or may not involve the active ingredient. When the active ingredient is involved, use of same or a chemically similar agent places the individual at risk for harm when the same or chemically similar agent is used. The subsequent reaction may be the same as the original reaction or a more exaggerated response may be seen, potentially placing the individual at even greater risk for harm.

If the reaction occurred from the active/main generic ingredient; request for branded agent with same active ingredient will not be considered unless it is proven (documented) that active ingredient did not cause reaction and the request meets other criteria within the coverage guideline

Intolerance – these events represent circumstance(s) where use of a drug produced a significant reaction and continued use may result in non-adherence to proposed therapy and this concern is documented in medical record

Contraindication

Use of a drug that is not recommended by the manufacturer or FDA labelling
Use of any drug in the face of a contraindication is outside of the FDA and manufacturer’s labelled recommendation and is considered investigational or experimental

Non-adherence
Individual does not follow prescribe regimen that places the individual at risk for lack of improvement or worsening of the condition being treated and this concern is documented in medical record

Precertification:

Precertification (Prior Authorization) is required for members with a Blue Cross Blue Shield of Arizona (BCBSAZ) pharmacy benefit for medication(s) or product(s) indicated in this guideline.

This Pharmacy Coverage Guideline does not apply to FEP or other states’ Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Criteria:

See “Resources” section for FDA-approved dosage.

- Precertification for Lidocaine external ointment USP, 5% requires completion of the specific request form in its entirety. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. Incomplete forms will be returned.

- **Initial therapy:** FDA-approved product labeling (indication, age, dosage, testing, contraindications, exclusions, etc.) of Lidocaine external ointment USP, 5%, is considered *medically necessary* when ALL of the following criteria are met:

  1. Medical record documentation of a confirmed diagnosis of **ONE** of the following:
     - Anesthetic lubricant for intubation
     - Production of anesthesia of accessible mucous membranes of the oropharynx
     - Temporary relief of pain associated with minor burns, including sunburn
     - Temporary relief of pain associated with abrasions of the skin
     - Temporary relief of pain associated with insect bites

  2. Medical record documentation that the individual is unable to use preferred agent(s) due to failure or adverse drug event:
LIDOCAINE external ointment USP, 5% (cont.)

- **For anesthetic lubricant for intubation**, unable to use **ALL** of the following:
  - Lidocaine 2% jelly
- **For production of anesthesia of accessible mucous membranes of the oropharynx**, unable to use **ALL** of the following:
  - Benzocaine 10% or 20% gel, liquid, ointment, or spray (prescription or over-the-counter)
  - Lidocaine 2% jelly
  - Lidocaine 4% solution
- **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**, unable to use **ALL** of the following:
  - Benzocaine 5% or 10% ointment or spray (prescription or over-the-counter)
  - Dibucaine 1% ointment (over-the-counter)
  - Pramoxine 1% cream, gel, lotion, or solution (prescription or over-the-counter)
  - Lidocaine 2% jelly
  - Lidocaine 3% or 3.25% cream

3. Absence of **ALL** of the following contraindications:
   - Individuals with a known history of hypersensitivity to local anesthetics of the amide type or to other components of Lidocaine ointment USP, 5%

- **Continuation of coverage (renewal request):** Lidocaine external ointment USP, 5% is considered **medically necessary** with documentation of **ALL** of the following:
  1. The individual has benefited from therapy but remains at high risk
  2. The condition has not progressed or worsened while on therapy
  3. Individual has not developed any contraindications or other exclusions to its continued use

- **Lidocaine external ointment USP, 5%** for all other indications not previously listed is considered **experimental or investigational** based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

**Resources:**


FDA-approved indication and dosage:

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<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose</th>
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<tr>
<td>Lidocaine Ointment USP, 5% is indicated for production of anesthesia of</td>
<td>When Lidocaine Ointment USP, 5% is used concomitantly with other products containing lidocaine USP, the total dose contributed by all formulations must</td>
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<td>accessible mucous membranes of the oropharynx.</td>
<td>be kept in mind.</td>
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<td><strong>Adult</strong></td>
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<td>A single application should not exceed 5 g of Lidocaine Ointment USP, 5%, containing 250 mg of lidocaine USP base (equivalent chemically to</td>
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<td>approximately 300 mg of lidocaine hydrochloride USP). This is roughly equivalent to squeezing a six (6) inch length of ointment from the tube. In</td>
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<td>a 70 kg adult this dose equals 3.6 mg/kg (1.6 mg/lb) lidocaine USP base. No more than one-half tube, approximately 17 g to 20 g of ointment or</td>
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<td>850 mg to 1000 mg lidocaine USP base, should be administered in any one day.</td>
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<td>Although the incidence of adverse effects with Lidocaine Ointment USP, 5% is quite low, caution should be exercised, particularly when employing</td>
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<td>large amounts, since the incidence of adverse effects is directly proportional to the total dose of local anesthetic agent administered.</td>
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<td><strong>Dosage for children</strong></td>
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<td>It is difficult to recommend a maximum dose of any drug for children since this varies as a function of age and weight. For children less than</td>
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<td>ten years who have a normal lean body mass and a normal lean body development, the maximum dose may be determined by the application of one of</td>
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<td>the standard pediatric drug formulas (e.g., Clark’s rule). For example a child of five years weighing 50 lbs., the dose of lidocaine USP should not</td>
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<td>exceed 75 mg to 100 mg when calculated according to Clark’s rule. In any case, the maximum amount of lidocaine administered should not exceed 4.5 mg/kg</td>
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<td>(2 mg/lb) of body weight.</td>
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