INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document (Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document) may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

NPF Medical Necessity

Drugs Affected
- lidocaine ointment 5% (generics)
- lidocaine jelly 2% (generics)
- lidocaine 2.5% and prilocaine 2.5% cream (Emla, generics)
- lidocaine 7% and tetracaine 7% cream (Pliaglis, generics)

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:
All approvals are provided for 12 months in duration unless otherwise noted below.

Lidocaine Ointment 5%

Maximum quantity per 30 days = 1 tube (35.44 gm or 50 gm)

Lidocaine Ointment 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. While there is no
frequency of administration listed in the prescribing information, medical literature reports typical administration of two times daily.

A quantity of one tube (35.44 or 50 grams) per 30 days will be covered without prior authorization. This is enough drug to cover 2% of the body surface area when applying two times daily for one month. For coverage of additional quantities (for example, coverage of a larger surface area, more frequent administration), a coverage review is required. The objective of this program is to prevent stockpiling, misuse and/or overuse.

**Lidocaine Ointment 5%**

1. For patients needing to produce anesthesia of accessible mucous membranes of the oropharynx greater than 2% of body surface area or administering more frequently than two times a day, an override of up to 150 grams per month can be allowed.

**Lidocaine Jelly 2%**

Lidocaine HCl 2% Jelly is indicated for 1) prevention and control of pain in procedures involving the male and female urethra, 2) for topical treatment of painful urethritis, 3) and as an anesthetic lubricant for endotracheal intubation (oral and nasal). Prior to catheterization, small volumes of 5 to 10 mL (100 to 200 mg) are usually adequate for lubrication. For surface anesthesia of the female adult urethra, 3 to 5 ml (60 to 100 mg) is instilled into the urethra. No more than 600 mg (30 ml) of lidocaine 2% should be administered in any 12 hour period for any of the listed indications.

A quantity of 60 ml per 30 days will be covered without prior authorization. For coverage of additional quantities (for example, routine self-catheterization), a coverage review is required. The objective of this program is to prevent stockpiling, misuse and/or overuse.

**Lidocaine 2.5% and prilocaine 2.5% cream**

Lidocaine and prilocaine cream (a eutectic mixture of lidocaine 2.5% and prilocaine 2.5%) is indicated as a topical anesthetic for use on normal intact skin for local analgesia of minor procedures such as intravenous cannulation and venipuncture, major dermal procedures such as split thickness skin graft harvesting, and genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia. The amount of cream required for topical anesthesia during a minor dermal procedure, such as intravenous cannulation and venipuncture is 2.5 grams according to prescribing information. The objective of this program is to prevent stockpiling, misuse and/or overuse.

A quantity of 30 gm per 30 days will be covered without prior authorization. This is enough drug to allow for six (6) separate dermal procedures utilizing 5 grams or twelve (12) separate dermal procedures utilizing 2.5 grams. For coverage of additional quantities (for example, more frequent dermal procedures requiring topical anesthesia), a coverage review is required. The objective of this program is to prevent stockpiling, misuse and/or overuse.

**Lidocaine 2.5% and prilocaine 2.5% cream**

1. For patients who need topical anesthesia for greater than twelve (12) separate dermal procedures (intravenous cannulation and venipuncture) utilizing 2.5 grams or six (6) separate dermal procedures (intravenous cannulation and venipuncture) utilizing 5 grams, an override of 30 grams can be approved for each additional twelve (12) minor dermal procedures (intravenous cannulation and venipuncture) utilizing 2.5 grams or each additional six (6) dermal procedures (intravenous cannulation and venipuncture) utilizing 5 grams per 30 days.
Lidocaine 7% and tetracaine 7% cream  

Pliaglis Cream is a combination of lidocaine and tetracaine that indicated for use on intact skin in adults to provide topical local analgesia for superficial dermatological procedures such as dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal. The objective of this program is to prevent stockpiling, misuse and/or overuse.

A quantity of 30 gm per 30 days will be covered without prior authorization. This is enough drug to allow for coverage of 250 square centimeter (38.7 square inch) area. For coverage of additional quantities (for example, more frequent dermal procedures requiring topical anesthesia), a coverage review is required. The objective of this program is to prevent stockpiling, misuse and/or overuse.

Lidocaine 7% and tetracaine 7% cream

All approvals are one-time approvals.

1. For patients who need topical anesthesia for greater than a 250 square centimeter (38.7 square inch), a one-time override of 30 grams can be approved for each additional 250 square centimeter (38.7 square inch) area needing topical anesthesia.

2. For patients who need topical anesthesia of a 250 square centimeter (38.7 square inch) greater than once per 30 days, a one-time override of 30 grams can be approved for each additional dermal procedure of a 250 square centimeter (38.7 square inch) area needing topical anesthesia.

Conditions Not Covered

Any other exception is considered not medically necessary, including the following:

Lidocaine Ointment 5%, Lidocaine Jelly 2%, Lidocaine 2.5% and prilocaine 2.5% cream

1. No overrides are recommended for use in compounded formulations.

2. No overrides are recommended for patients with peripheral or post-herpetic neuralgia, post-traumatic peripheral neuropathy, or peripheral diabetic neuropathy. Cochrane reviewed three trials that utilized lidocaine 8% spray or 5% gel in patients with peripheral herpetic neuralgia (PHN) or post-traumatic peripheral neuropathy, and a fourth trial where lidocaine 5% cream had been applied twice daily for 1 week in 30 patients who had PHN, peripheral diabetic neuropathy, or post-traumatic neuropathy. Based on this review, none of the non-patch lidocaine alternatives can be recommended as therapeutic options for treatment of peripheral neuropathic pain due to the relative absence of data.

3. No overrides are recommended for any other indications not listed in the prescribing information.

Lidocaine 7% and tetracaine 7% cream

1. No overrides are recommended for use in compounded formulations.

2. No overrides are recommended for patients with peripheral or post-herpetic neuralgia, post-traumatic peripheral neuropathy, or peripheral diabetic neuropathy. Cochrane reviewed three trials that utilized lidocaine 8% spray or 5% gel in patients with peripheral herpetic neuralgia (PHN) or post-traumatic peripheral neuropathy, and a fourth trial where lidocaine 5% cream had been applied twice daily for 1 week in 30 patients who had PHN, peripheral diabetic neuropathy, or post-traumatic neuropathy. Based on this review, none of the non-patch lidocaine alternatives can be recommended as therapeutic options for treatment of peripheral neuropathic pain due to the relative absence of data.

3. No overrides are recommended for cosmetic uses or indications (e.g., dermal filler injections, botulinum toxin injections; removal of spider angiomata; removal of telangiectasias; facial laser resurfacing; laser-assisted tattoo removal).
References

6. McPhee SJ, Papadakis MA: Current Medical Diagnosis and Treatment 2017, 56th Edition. Figure 37.2: 1560.

Revision History

<table>
<thead>
<tr>
<th>Type of Revision</th>
<th>Summary of Changes</th>
<th>Date</th>
</tr>
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<tbody>
<tr>
<td>Annual Revision</td>
<td>Reviewed by Clinical Specialists. No changes to criteria.</td>
<td>11/03/2020</td>
</tr>
<tr>
<td>Selected Revision</td>
<td>Added criteria to exclude overrides for cosmetic uses for Pliaglis. Reviewed and approved at TAC.</td>
<td>03/24/2021</td>
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