### BRAND NAME  
**EMLA**  
(lidocaine 2.5% and prilocaine 2.5% cream)  

- **lidocaine hcl 2% gel**  
- **lidocaine hcl 4% gel**  
- **lidocaine 5% ointment**  
- **lidocaine hcl 4% solution**  

**PLIAGLIS**  
(lidocaine and tetracaine 7-7% cream)  

**SYNERA**  
(lidocaine and tetracaine 70-70mg patch)  

**Type: Quantity Limit, Post Limit Prior Authorization**

### POLICY

**FDA-APPROVED INDICATIONS**

**Emla**  
Emla 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.  
- genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia.  

EMLA cream is not recommended in any clinical situation when penetration or migration beyond the tympanic membrane into the middle ear is possible because of the ototoxic effects observed in animal studies.

**Lidocaine 2% gel**  
Lidocaine hcl 2% gel is indicated for prevention and control of pain in procedures involving the male and female urethra, for topical treatment of painful urethritis, and as an anesthetic lubricant for endotracheal intubation (oral and nasal).

**Lidocaine 4% Gel**  
Lidocaine hcl 4% gel is indicated for the following:  
- Stage I - IV pressure ulcers  
- Venous stasis ulcers  
- Ulcerations caused by mixed vascular etiologies  
- Diabetic skin ulcers  
- First and second degree burns  
- Post-surgical incisions, cuts and abrasions

**Lidocaine 5% Ointment**  
Lidocaine 5% 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.
Lidocaine 4% Solution
Lidocaine hcl 4% topical solution is indicated for the production of topical anesthesia of accessible mucous membranes or the oral and nasal cavities and proximal portions of the digestive tract.

Pliaglis
Pliaglis cream is a combination of lidocaine, an amide local anesthetic, and tetracaine, an ester local anesthetic, and is 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.

Synera
Synera is a combination amide and ester local anesthetic indicated for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures such as excision, electrodessication and shave biopsy of skin lesions.

LIMIT CRITERIA
This quantity limit should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

<table>
<thead>
<tr>
<th>Drug</th>
<th>1 Month Limit and 3 Months Limit*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emla 2.5%-2.5% cream</td>
<td>30gm / 25 days</td>
</tr>
<tr>
<td>lidocaine -prilocaine 2.5-2.5% cream</td>
<td></td>
</tr>
<tr>
<td>Lidocaine 2% gel</td>
<td>30gm / 25 days</td>
</tr>
<tr>
<td>Lidocaine 4% gel</td>
<td>30gm / 25 days</td>
</tr>
<tr>
<td>Lidocaine 5% ointment</td>
<td>50gm / 25 days</td>
</tr>
<tr>
<td>Lidocaine 4% solution</td>
<td>50mL / 25 days</td>
</tr>
<tr>
<td>Pliaglis 7-7% cream</td>
<td>30gm / 25 days</td>
</tr>
<tr>
<td>Lidocaine-tetracaine 7-7% cream</td>
<td></td>
</tr>
<tr>
<td>Synera 70-70mg patch</td>
<td>2 patches / 25 days</td>
</tr>
<tr>
<td>Lidocaine-tetracaine 70-70mg patch</td>
<td></td>
</tr>
</tbody>
</table>

*The duration of 25 days is used for a 30-day fill period.

* These drugs are for short-term acute use; therefore, the mail limit will be the same as the retail limit.

COVERAGE CRITERIA
The requested drug will be covered with prior authorization when the following criteria are met:

- Lidocaine-prilocaine 2.5-2.5% cream is being prescribed as a topical anesthetic for use on either
  - Normal intact skin for local analgesia
  - Genital mucous membranes for superficial minor surgery and as pretreatment for infiltration anesthesia
  OR

- Lidocaine hcl 2% gel is being prescribed for any of the following:
  - Prevention and control of pain in procedures involving the male and female urethra
  - Topical treatment of painful urethritis
  - As an anesthetic lubricant for endotracheal intubation (oral and nasal)
  OR

- Lidocaine hcl 4% gel is being prescribed for any of the following:
  - Stage I - IV pressure ulcers
  - Venous stasis ulcers
  - Ulcerations caused by mixed vascular etiologies
  - Diabetic skin ulcers
  - First and second degree burns
- Post-surgical incisions, cuts and abrasions

**OR**
- Lidocaine 5% ointment is being prescribed for any of the following:
  - Production of anesthesia of accessible mucous membranes of the oropharynx
  - As an anesthetic lubricant for intubation
  - For the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites

**OR**
- Lidocaine hcl 4% topical solution is being prescribed for the production of topical anesthesia of accessible mucous membranes or the oral and nasal cavities and proximal portions of the digestive tract

**OR**
- Lidocaine-tetracaine 7-7% cream is being prescribed 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

**OR**
- Lidocaine-tetracaine 70-70mg patch is being prescribed for use on intact skin to provide local dermal analgesia for superficial venous access and superficial dermatological procedures such as excision, electrodessication and shave biopsy of skin lesions

**AND**
- The prescribed quantity falls within the manufacturer’s published dosing guidelines

**AND**
- If the requested drug will be used as part of a compounded product, all the active ingredients in the compounded product are FDA approved for topical use

*Quantity Limit may apply.

### POST LIMIT QUANTITY

This quantity limit should accumulate across all drugs and strengths up to highest quantity listed depending on the order the claims are processed. Accumulation does not apply if limit is coded for daily dose.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Quantities to approve per 25 days*</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMLA 2.5%-2.5% cream</td>
<td>60gm</td>
</tr>
<tr>
<td>lidocaine - prilocaine 2.5-2.5% cream</td>
<td></td>
</tr>
<tr>
<td>Lidocaine 2% gel</td>
<td>60gm</td>
</tr>
<tr>
<td>Lidocaine 4% gel</td>
<td>60gm</td>
</tr>
<tr>
<td>Lidocaine 5% ointment</td>
<td>100gm</td>
</tr>
<tr>
<td>Lidocaine 4% solution</td>
<td>100mL</td>
</tr>
<tr>
<td>Plagiis 7-7% cream</td>
<td></td>
</tr>
<tr>
<td>Lidocaine-tetracaine 7-7% cream</td>
<td>60gm</td>
</tr>
<tr>
<td>Synera 70-70mg patch</td>
<td>4 patches</td>
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<tr>
<td>Lidocaine-tetracaine 70-70mg patch</td>
<td></td>
</tr>
</tbody>
</table>

* These drugs are for short-term acute use; therefore, the mail limit will be the same as the retail limit.
REFERENCES
3. LDO Plus (Lidocaine 4% gel) [package insert]. Doral, FL: Gensco Laboratories, LLC; October 2015.

POLICY IMPLEMENTATION/REVISION INFORMATION
Prior Authorization
Original Implementation Date: 1/1/2017

| Revision Information |  |