

## PRIOR AUTHORIZATION POLICY

**POLICY:** Topical Anesthetic – Lidocaine, Tetracaine Products Prior Authorization with Step Therapy Policy

- Pliaglis® (lidocaine 7%/tetracaine 7% topical cream – Taro/Oba, generic)
- Synera® (lidocaine 70 mg/tetracaine 70 mg topical patches – Galen [obsolete 2022])

**REVIEW DATE:** 05/15/2024

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### OVERVIEW

Lidocaine 7%/tetracaine 7% topical cream (Pliaglis, generic) is indicated to provide topical local analgesia for **superficial dermatological procedures** (e.g., dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, laser-assisted tattoo removal) in adults, for use on intact skin.<sup>1</sup>

Synera is indicated to provide local dermal analgesia in patients  $\geq 3$  years of age on intact skin for the following uses:<sup>2</sup>

- **Superficial dermatological procedures.**
- **Venipuncture or intravenous cannulation.**

Lidocaine cream and combination lidocaine/prilocaine cream are other topical local anesthetics used for various conditions.<sup>3,4</sup>

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of lidocaine 7%/tetracaine 7% topical cream (Pliaglis, generic) and Synera. All approvals are provided for the duration noted below.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

- I.** Coverage of lidocaine 7%/tetracaine 7% topical cream (Pliaglis, generic) is recommended in those who meet the following criteria:

#### **FDA-Approved Indication**

- 1. Superficial Dermatological Procedures.** Approve for 1 week if the patient meets ALL of the following (A, B, C, and D):
  - A)** Patient is  $\geq 18$  years of age; AND
  - B)** The procedure is for a non-cosmetic condition; AND
  - C)** The medication will be applied to intact skin; AND
  - D)** Patient has tried both of the following topical anesthetics (i and ii):
    - i.** One lidocaine cream product; AND
    - ii.** One lidocaine/prilocaine cream product.

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Coverage of Synera is recommended in those who meet one of the following criteria:

### **FDA-Approved Indications**

- 1. Superficial Dermatological Procedures.** Approve for 1 week if the patient meets ALL of the following (A, B, C, and D):
  - A) Patient is  $\geq 3$  years of age; AND
  - B) The procedure is for a non-cosmetic condition; AND
  - C) The medication will be applied to intact skin; AND
  - D) Patient has tried both of the following topical anesthetics (i and ii):
    - i. One lidocaine cream product; AND
    - ii. One lidocaine/prilocaine cream product.
- 2. Venipuncture or Intravenous Cannulation.** Approve for 1 week if the patient meets ALL of the following (A, B, and C):
  - A) Patient is  $\geq 3$  years of age; AND
  - B) The medication will be applied to intact skin; AND
  - C) Patient has tried both of the following topical anesthetics (i and ii):
    - i. One lidocaine cream product; AND
    - ii. One lidocaine/prilocaine cream product.

### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of lidocaine 7%/tetracaine 7% topical cream (Pliaglis, generic) and Synera is not recommended in the following situations:

- 1. Cosmetic Conditions.** Cosmetic use is not recommended for coverage as this indication is excluded from coverage in a typical pharmacy benefit.  
Note: Examples of cosmetic conditions include dermal filler injection, pulsed dye laser therapy, facial laser resurfacing, and laser-assisted tattoo removal.
- 2.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### **REFERENCES**

1. Pliaglis® cream [prescribing information]. Hawthorne, NY: Taro; January 2021.
2. Synera® patches [prescribing information]. Souderton, PA: Galen; December 2020.
3. Lidocaine cream [prescribing information]. Livonia, MI: Rugby; March 2020.
4. Lidocaine and prilocaine cream [prescribing information]. Bridgewater, NJ: Amneal; April 2019.