



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

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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.¹

Synera is indicated to provide local dermal analgesia in patients ≥ 3 years of age on intact skin for the following uses:²

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

Lidocaine cream and combination lidocaine/prilocaine cream are other topical local anesthetics used for various conditions.^{3,4}

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.

- **Pliaglis® (lidocaine 7%/tetracaine 7% topical cream (Taro/Oba, generic)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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.

- **Synera® (lidocaine 70 mg/tetracaine 70 mg topical patches – Galen [obsolete 2022])**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

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

is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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.

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.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	05/24/2023
Annual Revision	No criteria changes.	05/15/2024

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