# MEDICAL POLICY

Capital BLUE

| POLICY TITLE | IONTOPHORESIS/ PHONOPHORESIS |
|---|---|
| POLICY NUMBER | MP-4.013 |

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|---|---|
| **Original Issue Date (Created):** | **7/12/2002** |
| **Most Recent Review Date (Revised):** | **2/19/2021** |
| **Effective Date:** | **8/1/2021** |



## I. POLICY

Iontophoresis may be considered **medically necessary** to administer local anesthesia prior to a venipuncture.

Iontophoresis of fentanyl may be considered **medically necessary** for the short-term (i.e., less than 24 hours) management of acute postoperative pain in adult patients requiring opioid analgesia in a monitored facility (e.g., inpatient hospital, outpatient hospital, ambulatory surgical center).

Iontophoresis as a transdermal drug delivery technique for other medical indications is considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with the above procedures.

Phonophoresis alone or in combination with iontophoresis as a transdermal drug delivery technique is considered **investigational.** There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with the above procedures.

NOTE: For Iontophoresis for the treatment of Hyperhidrosis - see MP 2.005 Non-pharmacological treatments of hyperhidrosis

***Cross-References:***

**MP-2.005** Non-Pharmacological Treatments of Hyperhidrosis

## II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

**FEP PPO:** The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore,

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FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

## III. DESCRIPTION/BACKGROUND

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Iontophoresis/phonophoresis – These modalities utilize electric current (iontophoresis) or ultrasound energy (phonophoresis) to force a therapeutic medication (eg, glucocorticoid) into tissue

Iontophoresis is a method of introducing charged, ionic drugs through the skin by administering direct electrical current into the tissues of the body. The ionic drug is placed on the skin with an electrode of the same charge, allowing the direct current to drive the drug into the skin.

Iontophoresis has been used for delivering local anesthetic before skin puncture or other painful dermal procedures, local drug delivery for agents such as nonsteroidal and anti-inflammatory drugs, or corticosteroids for musculoskeletal inflammatory disorders. In the treatment of musculoskeletal disorders, iontophoresis is usually offered in the physical medicine and rehabilitation setting.

Iontophoresis used in conjunction with tap water or anticholinergic agents is a long-standing treatment of palmar (palms) or plantar (soles) and more recently axillary (underarm) idiopathic hyperhidrosis. The mechanism of action is not precisely known, but it is thought to be related to plugging of the sweat glands. During this procedure, trays are filled with tap water and the patient inserts the hands or feet or positions the device in the axilla, and the current is turned on. Patients are treated for approximately twenty (20) minutes, with treatments every two (2) to three (3) days for five (5) to ten (10) sessions before an effect is observed. Maintenance therapy may be required every two (2) weeks after normal sweating is achieved.

Iontophoresis should not be performed on patients with pacemakers or other electrically sensitive implanted devices, patients with a known sensitivity to electric currents, or patients with allergies to the drug being administered or to electrode adhesives. Iontophoresis electrodes should not be applied to damaged, blemished or recently scarred skin.

A number of iontophoresis devices have received 510(k) marketing clearance from the Food and Drug Administration (FDA) to “introduce ions of soluble salts or other drugs into the body.” The FDA prohibits labeling or promoting their use with specific drugs prior to the FDA having specifically approved the drugs for iontophoretic administration. The IONSYS™ fentanyl iontophoretic transdermal system received FDA first-generation approval on May 2006. The second generation fentanyl ITS was approved on April 2015 for the short-term management of acute postoperative pain in adults patients requiring opioid analgesia in hospital. In November 2015, EC approval was given for acute moderate to-severe postoperative pain in adult patients for

use in the hospital. The SonoPrep® (Echo Therapeutics, Inc.) phonophoresis device is cleared by the FDA as class 2 electromedical equipment. SonoPrep® uses low frequency ultrasound to enhance skin permeability.

## IV. RATIONALE

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**Summary**

The available evidence for the use of iontophoresis to administer local anesthesia prior to a venipuncture or dermatologic procedure, and fentanyl for the short-term (i.e., less than 24 hours) management of acute postoperative pain in adult patients is sufficient to show improvement in net health outcome.

Given the lack of evidence to show improvement in net health outcome, phonophoresis as a transdermal delivery technique, alone or in combination with iontophoresis, remains **investigational.**

## V. DEFINITIONS

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**ANTICHOLINERGIC** is an agent that blocks acetylcholine receptors resulting in the inhibition of the transmission of parasympathetic nerve impulses with resulting side effects of reducing salivary and bronchial secretions and decreasing perspiration.

**HYPERHIDROSIS** refers to sweating greater than would be expected considering the temperature of the environment.

**IDIOPATHIC** refers to conditions without a known cause.

**IONIC** refers to ions; in aqueous solutions, ions are electrolytes because they permit the solution to conduct electricity**.**

## VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital BlueCross for benefit information.

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## VII. DISCLAIMER

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*Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

## VIII. CODING INFORMATION

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**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

**Investigational; therefore, not covered for phonophoresis as a transdermal drug delivery technique:**

| CPT Codes ® | | | | | | | |
|---|---|---|---|---|---|---|---|
| 97035 | | | | | | | |



**Covered when medically necessary:**

| CPT Codes ® | | | | | | | |
|---|---|---|---|---|---|---|---|
| 97033 | | | | | | | |



| HCPCS Code | Description |
|---|---|
| J3010 | Injection, fentanyl citrate, 0.1 mg |

| ICD-10-CM Diagnosis Code | Description |
|---|---|
| G89.18 | Other acute postprocedural/postoperative pain |

## IX. REFERENCES

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1. *2003 TEC Assessments: Tab 3.*
2. *2000 TEC Assessments: Tab 20.*
3. *Chelly JE, Grass J, Houseman TW et al. The safety and efficacy of a fentanyl patient-controlled transdermal system for acute postoperative analgesia: a multicenter, placebo-controlled trial. Anesth Analg 2004; 98(2):427-33.*
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***Other:***

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## X. POLICY HISTORY

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|---|---|
| **MP 4.013** | **CAC 12/2/03** |
| | **CAC 4/26/05** |
| | **CAC 5/30/06** |
| | **CAC 4/24/07 Consensus review** |
| | **CAC 1/29/08** |
| | **CAC 1/27/09** |
| | **CAC 1/26/10 Consensus review** |
| | **CAC 4/26/11 Minor review.** Deleted information related to Hyperhidrosis. Reference to new policy MP-2.005 Treatment of Hyperhidrosis added. |
| | **CAC 10/30/12 Consensus review**. No change to policy statements. References updated. Codes reviewed 10/23/12 |

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| | **CAC 11/26/13 Consensus review**. References updated, but no changes to the policy statements. Rationale added. |
| | **CAC 11/25/14 Consensus review**. No change to policy statements. References updated. Codes reviewed |
| | **CAC 11/24/15 Consensus review**. No changes to the policy statements. Reference update**.** LCD number changed from L27513 to LCD L35044 due to ICD-10 Novitas update. Coding updated. |
| | **5/9/16 Medicare update.** Changed LCD variation to reference L35036 Therapy and Rehabilitation Services (PT, OT). L35044 Physical Medicine & Rehabilitation Services, Physical Therapy and Occupational Therapy retired by Novitas. |
| | **CAC 9/27/16 Consensus review**. No change to the policy statements**.** Variations reformatted. Coding reviewed. |
| | **CAC 11/28/17 Consensus review**. No change to policy statements. References and rationale reviewed. Coding Reviewed. |
| | **7/30/18 Consensus review**. No change to the policy statement. References reviewed. Rationale revised. |
| | **05/20/19 Consensus review**. No change to policy statements. |
| | **05/07/20 Consensus review**. References updated no change to policy statements. |
| | **2/19/21 Consensus review.** No change to policy statement. Added note to refer to MP 2.005 for Non-pharmacological treatments of hyperhidrosis. Minor revisions under description/background, rationale and definition section. References updated. |

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