MEDICAL POLICY

POLICY TITLE	IONTOPHORESIS/ PHONOPHORESIS
POLICY NUMBER	MP 4.013

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**3/1/2024**

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 adults 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 general conclusion concerning the health outcomes or benefits associated with the above procedures.

Note: For Iontophoresis for the treatment of Hyperhidrosis - see MP 2.005 Other Therapies of Hyperhidrosis

Cross-References:

MP 2.005 Non-Pharmacological Treatments of Hyperhidrosis

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

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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 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.

Phonophoresis, or sonophoresis, is defined as the use of ultrasonic energy in order to enhance the topical or transdermal delivery of drugs. Phonophoresis provides higher local concentrations of the drug than with simple topical application, increasing permeability through structural changes in the skin, as well as through the convection mechanisms inherent to the ultrasound effect.

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 Top

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 Top

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER Top

Capital Blue Cross'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 Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION Top

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:

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Procedure Codes							
97035							

Covered when medically necessary:

Procedure Codes							
J3010	97033						

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

IX. REFERENCES

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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

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	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
	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.
	1/4/22 Consensus review. No change to policy statement. Product and Benefit Variations updated**.** References reviewed and updated.
	08/07/2023 Consensus review. No changes to policy statement. Updated background and references.
	1/19/2024 Administrative update. Clinical benefit added.

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