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# Medical Policy Iontophoresis and Phonophoresis as a Transdermal Technique for Drug Delivery

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# Policy Number: 095

BCBSA Reference Number: 8.03.14A (For Plan internal use only)

# **Related Policies**

Treatment of Hyperhidrosis (includes iontophoresis as treatment of hyperhidrosis), #406

#### Policy Commercial Members: Managed Care (HMO and POS), PPO and Indemnity

lontophoresis to administer local anesthesia prior to a venipuncture or dermatologic procedure may be <u>MEDICALLY NECESSARY</u>.

lontophoresis of fentanyl 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) may be <u>MEDICALLY NECESSARY</u>.

lontophoresis as a transdermal drug delivery technique for other medical indications is **INVESTIGATIONAL**.

Phonophoresis alone or in combination with iontophoresis as a transdermal drug delivery technique for any medical indication is **INVESTIGATIONAL**.

# **Prior Authorization Information**

### Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

Outpatient

 For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>not required</b> .
Commercial PPO and Indemnity	Prior authorization is <b>not required</b> .

# **CPT Codes / HCPCS Codes / ICD Codes**

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

# The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

### **CPT Codes**

CPT codes:	Code Description
97033	Application of a modality to 1 or more areas; iontophoresis, each 15 minutes

According to the policy statement above, the following CPT codes are considered investigational for the conditions listed for <u>Commercial Members: Managed Care (HMO and POS), PPO, and</u> <u>Indemnity:</u>

### **CPT Codes**

CPT codes:	Code Description
97035	Application of a modality to 1 or more areas; ultrasound, each 15 minutes
99070	Supplies and materials (except spectacles), provided by the physician or other qualified health care professional over and above those usually included with the office visit or other services rendered (list drugs, trays, supplies, or materials provided)

### **Description**

Iontophoresis is a method of transdermal local drug delivery using electrical current. A charged ionic drug is placed on the skin with an electrode of the same charge, allowing direct current to drive the drug into the skin, where it is absorbed into the bloodstream and into deeper structures underlying the skin. Ultrasound transdermal delivery involves the use of ultrasonic energy to enhance delivery of solutes either simultaneously or via pre-treatment and is referred to as sonopheresis or phonophoresis. The proposed mechanism for phonophoresis is to increase skin permeability by the formation of gaseous cavities within the intracellular lipids on exposure to ultrasound.

Iontophoresis has been proposed for numerous uses, including delivery of local anesthetic before skin puncture or other painful skin procedures, local drug delivery for agents such as nonsteroidal antiinflammatory drugs (NSAIDs) or corticosteroids for musculoskeletal inflammatory disorders Examples of iontophoresis devices for transdermal local drug delivery include the ONSYS<sup>™</sup> fentanyl iontophoretic transdermal system from ALZA and All iontophoresis devices for transdermal local drug delivery for ultrasound transdermal delivery are considered investigational regardless of the commercial name, the manufacturer or FDA approval status, except as noted in the policy statement.

Examples of phonophoresis devices for ultrasound transdermal delivery include the SonoPrep® device from Echo Therapeutics, Inc. All phonophoresis devices for ultrasound transdermal delivery are considered investigational regardless of the commercial name, the manufacturer or FDA approval status.

### 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. Therefore, their use for these indications may be medically necessary.

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

Date	Action
1/2023	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
10/2022	Annual policy review. Policy updated with literature review through October 2022. No references added. Policy statements unchanged.
4/2020	Policy updated with literature review through March 27, 2020, no references added. Policy statements unchanged.
9/2015	Clarified coding language.
11/2011-	Medical policy ICD 10 remediation: Formatting, editing and coding updates.
4/2012	No changes to policy statements.
6/2011	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation and Rheumatology. No changes to policy statements.
7/2010	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation and Rheumatology. No changes to policy statements.
7/2010	Annual policy review. Changes to policy statements.
12/1/2009	Annual policy review. Changes to policy statements.
7/2009	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation and Rheumatology.
	No changes to policy statements.
5/2009	Annual policy review. Changes to policy statements.
2/1/2009	New policy, effective 2/1/2009, describing covered and non-covered indications.

### **Policy History**

# Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use Managed Care Guidelines Indemnity/PPO Guidelines Clinical Exception Process Medical Technology Assessment Guidelines

### References

- 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.
- 4. Viscusi ER, Reynolds L, Tait S et al. An iontophoretic fentanyl patient-activated analgesic delivery system for postoperative pain: a double-blind, placebo-controlled trial. Anesth Analg 2006; 102(1):188-94.
- 5. Hartrick CT, Bourne MH, Gargiulo K et al. Fentanyl iontophoretic transdermal system for acute-pain management after orthopedic surgery: a comparative study with morphine intravenous patient-controlled analgesia. Reg Anesth Pain Med 2006; 31(6):546-54.
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- 8. Vranken JH, Dijkgraaf MG, Kruis MR et al. Iontophoretic administration of S(+)-ketamine in patients with intractable central pain: a placebo-controlled trial. Pain 2005; 118(1-2):224-31.
- Nirschl RP, Rodin DM, Ochiai DH et al. for the DEX-AHE-01-99 Study Group. Iontophoretic administration of dexamethasone sodium phosphate for acute epicondylitis. A randomized, doubleblinded, placebo-controlled study. Am J Sports Med 2003; 31(2):189-95.
- 10. Neeter C, Thomee R, Silbernagel KG et al. Iontophoresis with or without dexamethazone in the treatment of acute Achilles tendon pain. Scand J Med Sci Sports 2003; 13(6):376-82.
- 11. Osborne HR, Allison GT. Treatment of plantar fasciitis by LowDye taping and iontophoresis: short term results of a double blinded, randomised, placebo controlled clinical trial of dexamethasone and acetic acid. Br J Sports Med 2006; 40(6):545-9.
- Leduc BE, Caya J, Tremblay S et al. Treatment of calcifying tendinitis of the shoulder by acetic acid iontophoresis: a double-blind randomized controlled trial. Arch Phys Med Rehabil 2003; 84(10):1523-7.
- 13. Amirjani N, Ashworth NL, Watt MJ et al. Corticosteroid iontophoresis to treat carpal tunnel syndrome: a double-blind randomized controlled trial. Muscle Nerve 2009; 39(5):627-33.
- 14. Gurney AB, Wascher DC. Absorption of dexamethasone sodium phosphate in human connective tissue using iontophoresis. Am J Sports Med 2008; 36(4):753-9.
- 15. Turner J, Belch JJ, Khan F. Current concepts in assessment of microvascular endothelial function using laser Doppler imaging and iontophoresis. Trends Cardiovasc Med 2008; 18(4):109-16.
- 16. Rao R, Nanda S. Sonophoresis: recent advancements and future trends. J Pharm Pharmacol 2009; 61(6):689-705.
- 17. Zelrix<sup>™</sup> Transdermal Treatment for Acute Migraine, NuPathe®, Inc. (not FDA approved). Available at: <u>http://www.nupathe.com/description-3-5/research\_and\_development\_\_zelrix\_-\_acute\_migraine.html</u>.