Anthem

Clinical UM Guideline

Subject: Iontophoresis
Guideline #: CG-MED-28
Status: Reviewed

Publish Date: 01/03/2024
Last Review Date: 11/09/2023

Description

This document addresses the use of iontophoresis, the passing of an ionized substance through intact skin by the application of a direct electrical current. It has been evaluated as a technique for drug delivery and proposed as a treatment for hyperhidrosis.

Clinical Indications

Medically Necessary:

Iontophoresis is considered **medically necessary** for *any* of the following indications:

A. For the administration of local anesthesia prior to a venipuncture or dermatologic procedure; **or**
B. In the treatment of primary or secondary hyperhidrosis only for individuals who have tried prescription strength antiperspirants without success and meet any ONE of the following criteria:
    1. Presence of medical complications or skin maceration with secondary infection; **or**
    2. Significant functional impairment, as documented in the medical record.

Not Medically Necessary:

The use of iontophoresis is considered **not medically necessary** when the above criteria are not met and for all other indications, including, but not limited to treatment of temporomandibular disorders, and as a technique for drug delivery involving the administration of nonsteroidal anti-inflammatory drugs (NSAIDs) or corticosteroids as treatment for inflammatory musculoskeletal disorders.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
97033	Application of a modality to one or more areas; iontophoresis, each 15 minutes
HCPCS	
E1399	Durable medical equipment, miscellaneous [when specified as an iontophoresis device for home use]
ICD-10 Diagnosis	
	All diagnoses, including but not limited to the following
L74.510-L74.519	Primary focal hyperhidrosis
L74.52	Secondary focal hyperhidrosis
R61	Generalized hyperhidrosis

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met, for all other indications including for the following diagnosis codes, or for situations designated in the Clinical Indications section as not medically necessary.

ICD-10 Diagnosis	
G44.89	Other headache syndrome
M19.09	Primary osteoarthritis, other specified site
M19.91	Primary osteoarthritis, unspecified site
M26.50-M26.59	Dentofacial functional abnormalities
M26.601-M26.69	Temporomandibular joint disorders
M79.10-M79.12	Myalgia, unspecified; mastication muscle; auxiliary muscles, head and neck
S03.00XA-S03.03XS	Dislocation of jaw

Discussion/General Information

Iontophoresis is a method of transdermal local ion delivery using electrical current. A charged ionic substance is placed on the skin with an electrode of the same charge, allowing direct current to drive the substance into the skin. Iontophoresis may take advantage of sweat ducts, sebaceous glands, hair follicles, and imperfections in the skin to achieve penetration. Alternatively, electrical potential across the skin could alter its permeability, possibly creating potential-dependent pores in lipid bilayer membranes.

Drug Delivery

Iontophoresis has been proposed for numerous uses including the delivery of local anesthetic before skin puncture or painful dermal procedures and for local drug delivery for agents including, but not limited to, NSAIDs, corticosteroids for musculoskeletal inflammatory disorders, or verapamil for the treatment of Peyronie's disease. Overall, the results published in the peer-reviewed medical literature include small randomized, placebo-controlled or comparative trials and non-randomized retrospective studies. The study results, reported as treatment outcome measurements, do not support the iontophoretic application of NSAIDs, corticosteroids,

or other drugs for the treatment of carpal tunnel syndrome (Amirjani, 2009; Bakhtiary, 2013; Gurcay, 2012), chronic foot eczema (Tupker, 2013), epicondylitis (Nirschl, 2003), intractable central pain (Vranken, 2005), keratoconus (Lombardo, 2017; Lombardo, 2019; Vinciguerra, 2019), migraine headache (Pierce, 2010), onychomycosis (Amichai, 2010), patellar tendinopathy (Rigby, 2015), plantar fasciitis (Allison, 2006), recalcitrant scarring after open trigger finger release (Dardas, 2014), rotator cuff disease (Page, 2016), tendonitis (Leduc, 2003; Neeter, 2003), trapezial-metacarpal joint arthritis (Jain, 2010), or verapamil (with or without dexamethasone or in combination therapy) for the treatment of Peyronie's disease (Bennett, 2007; Greenfield, 2007; Mehrsai, 2013; Paulis, 2013).

In a Cochrane review, Kroeling and colleagues (2013) evaluated the short-, intermediate- and long-term effects of electrotherapy, including iontophoresis, on pain, function, disability, patient satisfaction, global perceived effect, and quality of life in adults with neck pain with and without radiculopathy or cervicogenic headache. The effects of iontophoresis versus no treatment were evaluated in a single study of very low quality evidence and a high risk of bias. No difference between the groups was reported in cervicogenic headache or neck pain relief after 5 weeks of treatment. When direct current iontophoresis combined with diclofenac gel was compared to interferential current and multimodal treatment (that is, traction, therapeutic exercise, and massage), no difference between the groups was reported in cervicogenic headache or neck pain after 5 weeks of treatment. The authors concluded that for individuals with acute whiplash, iontophoresis was no more effective than no treatment, interferential current, or a combination of traction, exercise and massage for relieving neck pain with headache.

Sayegh and Strauch (2014) performed a meta-analysis of randomized controlled trials (RCTs) comparing any form of nonsurgical treatment, including corticosteroid iontophoresis, with either observation only or placebo at 6 months or greater follow-up for the treatment of lateral epicondylitis. The primary objective was to establish the superiority of nonsurgical treatments over non-treatment in the following outcomes: "(1) better overall improvement, (2) less need for escape interventions, (3) better outcome scores, and (4) improved grip strength at intermediate- to long-term follow-up." A total of 22 studies with intermediate- to long-term follow-up met the inclusion criteria; however, only 1 small study (n=64) of "good methodologic quality" and short duration (6 months) compared the use of corticosteroid iontophoresis to placebo. Pooled data from all RCTs indicated a lack of intermediate- to long-term clinical benefit after nonsurgical treatment of lateral epicondylitis compared with observation only or placebo, including the use of corticosteroid iontophoresis.

Iontophoresis is considered in accordance with generally accepted standards of medical practice for the administration of local anesthesia prior to a venipuncture or dermatologic procedure. A number of studies have demonstrated that iontophoresis appears to be a safe and effective method of local anesthesia delivery for procedures in children (DeCou, 1999; Zempsky, 2003; Lustig, 2020) and adults (Arvidsson, 1984; Zempsky, 2004). Lidocaine iontophoresis provides effective pain relief for venous catheter placement or venipuncture within 10 to 20 minutes (Squire, 2000; Zempsky, 1998). However, the emergence of liposomal lidocaine as a topical anesthetic that has an onset of action similar to iontophoresis has resulted in less frequent use of iontophoresis in clinical practice.

The U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for a number of iontophoresis devices 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 approved the drugs for iontophoretic administration (FDA, 2023).

Hyperhidrosis

Hyperhidrosis is a relatively uncommon condition of exaggerated perspiration due to excessive secretion of the eccrine sweat glands in amounts greater than required for physiologic needs of thermoregulation and electrolyte alteration (Nawrocki, 2019). Primary hyperhidrosis is idiopathic in nature, typically involving the hands (palmar), feet (plantar) or armpits (axillae). Secondary hyperhidrosis can result from a variety of drugs, such as tricyclic antidepressants, selective serotonin reuptake inhibitors (SSRIs), or underlying disease/conditions, such as febrile disease, diabetes mellitus or menopause. Gustatory hyperhidrosis may be primary or secondary in nature, but is usually considered separately from these two classes of hyperhidrosis. As a primary condition, it is characterized by excessive sweating of the lips, nose, and forehead after eating certain foods. As a secondary condition, this sweating condition is the result of complications from surgery to the parotid gland and subsequent aberrant regenerating parasympathetic fibers.

The consequences of hyperhidrosis are primarily psychosocial in nature. Excessive sweating may be socially embarrassing, may require several changes of clothing a day or result in staining of clothing or shoes. In some situations, hyperhidrosis may interfere with the activities of daily living. For example, palmar hyperhidrosis may interfere with those jobs that require detailed work with the hands.

Treatment of secondary hyperhidrosis naturally focuses on treatment of the underlying cause. A variety of therapies have been investigated for primary hyperhidrosis, including topical therapy with aluminum chloride or tanning agents, iontophoresis, and endoscopic transthoracic sympathectomy.

Iontophoresis for hyperhidrosis involves the introduction of an electrical current through the skin using water as a medium. Iontophoresis is a long-standing method of treatment for palmar or plantar hyperhidrosis with a reported success rate of up to 85% (Levit, 1980; Pariser, 2014). The mechanism of action of iontophoresis is not precisely known but is thought to be related to plugging of the sweat gland pores. The typical device consists of water-filled trays containing electrodes. A special axillary electrode can be used in the treatment of axillary hyperhidrosis, but this treatment is often less effective because of difficulty obtaining uniform contact of the electrode with the axillary skin. The individual inserts the hands or feet in the tray or positions the electrode in the axilla, and the current is turned on. Individuals are treated for approximately 20 minutes, with treatments every 2 to 5 days for 5 to 10 sessions before an effect is observed. Maintenance therapy may be required every 2 weeks after a normal level of sweating is achieved. Treatment may be uncomfortable and, in some cases, painful. Potential side effects include dry, cracked hands or feet, skin erythema, and transient vesiculation. Nonetheless, treatment of primary or secondary hyperhidrosis with iontophoresis is considered in accordance with generally accepted standards of medical practice only for individuals who have tried prescription strength antiperspirants without success when medical complications or skin maceration with secondary infection is present or when hyperhidrosis results in significant functional impairment.

Several iontophoresis devices have been approved by the FDA. There are some machines that can only be used by physicians in an office setting. Four commercially available machines are intended for home use by individuals with a prescription. These devices are the Drionic® device (General Medical Co., Los Angeles, CA), the Dermadry® device (Dermadry Laboratories Inc., Montreal, QC), the Hidrex device (Hidrex USA, Austin, TX), and the Fischer™ MD-1a Galvanic Unit (R.A. Fischer Co., Northridge, CA.).

Definitions

Eccrine gland: A gland in the skin that secretes sweat. These glands are located all over the body, and greater concentrations may be found in certain areas of the body such as the armpits, feet, and hands.

Functional impairment: Significant functional impairment may include physical, social, emotional, and psychological impairments or potential impairments.

Hyperhidrosis: Severe and uncontrollable localized sweating of the scalp, torso (truncal), face (facial) hands (palmar), underarms (axillary), or the feet (plantar or pedal).

Iontophoresis: The passing of an ionized substance through intact skin by the application of a direct electrical current.

Primary hyperhidrosis: Hyperhidrosis due to unknown causes.

Secondary hyperhidrosis: Hyperhidrosis that results from an underlying cause; some common causes include prescribed drug side-effects and medical conditions such as anxiety disorders, diabetes mellitus, and menopause.

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Websites for Additional Information

1. American Academy of Dermatology. Hyperhidrosis: Diagnosis and Treatment. Available at: https://www.aad.org/public/diseases/a-z/hyperhidrosis-treatment. Accessed on August 16, 2023.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Discussion/General Information, References, Websites for Additional Information and Index sections.
Revised	11/10/2022	MPTAC review. Moved indications for iontophoresis from CG-MED-63 and CG-SURG-09 to this document. Added Definitions, Websites for Additional Information, and Index sections. Added MN criteria for iontophoresis for hyperhidrosis. Revised NMN criteria to include treatment of temporomandibular disorders. Updated Description, Discussion/General Information and References sections. Updated Coding section to add E1399 NOC.
Revised	11/11/2021	MPTAC review. Title change to “Iontophoresis” from “Iontophoresis for Medical Indications”. Updated References section.
Reviewed	11/05/2020	MPTAC review. Updated References section. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review. Updated Discussion and References sections.
Reviewed	11/08/2018	MPTAC review. Updated Discussion and References sections.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Description, Discussion, and References sections.
Reviewed	02/02/2017	MPTAC review. Updated Discussion/General Information and References sections.
Reviewed	02/04/2016	MPTAC review. Updated Discussion/General Information and References sections. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Updated Description, Discussion, and References sections.
Reviewed	02/13/2014	MPTAC review. Updated Discussion and References sections.
Reviewed	02/14/2013	MPTAC review. Updated Discussion and References. Removed Index.
Reviewed	02/16/2012	MPTAC review. Updated References.
Reviewed	02/17/2011	MPTAC review. Updated Discussion, Coding, and References.
Reviewed	02/25/2010	MPTAC review. Updated Discussion and References. Removed sections: Place of Service and Discharge Plans.
Reviewed	02/26/2009	MPTAC review. Updated References.
Reviewed	02/21/2008	MPTAC review. Updated Discussion and References.
Revised	03/08/2007	MPTAC review. Clinical Indications revised/clarified. Discussion, References and Coding updated.
New	03/23/2006	MPTAC initial document development.

Pre-Merger Organizations	Last Review Date	Document Number	Title
Anthem, Inc.		None	
Anthem Virginia	05/10/2004	Memo 1192	Iontophoresis for Medical Indications
WellPoint Health Networks, Inc.		None	