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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Iontophoresis

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Non-Covered Services (L35008).
Local Coverage Article	None

For Non-Medicare Members

Kaiser Permanente has elected to use the Iontophoresis (KP-0617) MCG* for medical necessity determinations.

> ***The MCG are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

For Medication Delivery with Iontophoresis for Temporomandibular Joint (TMJ) Dysfunction and Joint Pain or Devices for use in the member's home.

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Evidence and Source Documents

Iontophoresis for Hyperhydrosis using Drionic or Idrostar Devices
Iontophoresis for Joint Pain
Medication Delivery with Iontophoresis for Temporomandibular Joint (TMJ) Dysfunction

Background

Iontophoresis is the use of electricity to enhance the percutaneous absorption of a drug or chemical ions. Ions in solution are transferred through the skin by passing DC electrical current between two electrodes. Iontophoresis uses a low current and patients' have little or no sensation during the procedure. Drugs used in iontophoresis should be those that ionize. Drugs used for iontophoresis may include lidocaine hydrochloride (a positive ion forming drug) and dexamethasone sodium phosphate (a negative ion forming drug). Possible advantages include greater convenience and less discomfort compared to injection, less variation in absorption, and fewer side effects compared to oral administration of medication.

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Medical Technology Assessment Committee (MTAC)

Iontophoresis for Hyperhydrosis using Drionic or Idrostar Devices

BACKGROUND

Hyperhydrosis or excessive sweating may be classified into primary or essential hyperhydrosis with an unknown cause, and secondary hyperhydrosis which is due to an underlying condition as hyperthyroidism, menopause, obesity, psychiatric disorder, and others. It may be localized in one or several locations of the body, most often in the hands (palmer hyperhydrosis) but may also be planter, axillary, facial, or general. Several methods are used to treat patients with primary hyperhydrosis, or secondary cases with heavy sweating or untreatable conditions. These include the use of antiperspirants, drugs, psychotherapy, surgery, iontophoresis, use of botulinum toxin, alternative medicine, and others. Iontophoresis can be defined as a means of delivering medication to a localized tissue area by applying electrical current to a solution of the medication. It consists of applying low intensity current (15-18 mA) supplied by a D/C generator to the palms and/or soles immersed in an electrolyte solution. The procedure has to be repeated regularly, and the results may vary among patients. The Drionic and Idrostar devices are battery- operated methods of inducing tap water iontophoresis.

06/12/2002: MTAC REVIEW

Iontophoresis for Hyperhydrosis using Drionic or Idrostar Devices

Evidence Conclusion: There is not enough evidence to permit conclusions on the use of either the Drionic or Idrostar device for treating hyperhydrosis.

Articles: The search yielded three articles, two of which were reviews, and the third was a small case series with 22 patients with hyperhydrosis treated with the Drionic unit.

The use of idrostar in the treatment of hyperhydrosis via iontophoresis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/03/2009: MTAC REVIEW

Iontophoresis in the Treatment of Hyperhydrosis

Evidence Conclusion: There is insufficient evidence to draw conclusions on the safety and efficacy of iontophoresis for treating hyperhydrosis. No published comparative studies were identified. The literature base consists of case series, mostly with fewer than 25 patients and one case series with 112 patients. The larger series reported that about 81% of participants responded to treatment. The criteria provided for response was not clearly defined and there was no long-term follow-up.

Articles: Four empirical studies specifically evaluating iontophoresis for hyperhidrosis were identified. There were no randomized or non-randomized controlled studies. All of the empirical studies were case series. Three had fewer than 25 patients and were excluded from further review. The fourth (Karakoc et al., 2002) included 112 patients and was critically appraised. See Evidence Table.

The use of iontophoresis in the treatment of hyperhydrosis does not meet the Kaiser Permanente *Medical Technology Assessment Criteria.*

Iontophoresis for Joint Pain

BACKGROUND

Iontophoresis is proposed as a treatment for joint pain. It has been used for various types of tendonitis including epicondylitis, patellar tendonitis, biceps tendonitis, rotator cuff tendonitis and Achilles tendonitis (Winn, unpublished manuscript). Iontophoresis is the use of electricity to enhance the percutaneous absorption of a drug or chemical ions. Ions in solution are transferred through the skin by passing DC electrical current between two electrodes. Iontophoresis uses a low current and patients have little or no sensation during the procedure. Drugs used in iontophoresis should be those that ionize. Dexamethasone sodium phosphate, a negative ion, is a commonly used drug used for iontophoresis treatment of joint pain. Possible advantages include greater convenience and less discomfort compared to injection, less variation in absorption, and fewer side effects compared to oral administration of medication. Common treatments for joint pain include rest, ice after exercise, stretching, bracing and immobilization; medications such as analgesics and non-steroidal anti-inflammatory drugs (NSAIDs) and injection of corticosteroids. A well-done randomized controlled trial (Hay et al., 1999) found that local injection of corticosteroid was more effective for treating lateral epicondylitis than NSAID treatment, but that more than 80% of patients were improved at 12 months regardless of treatment.

10/08/2003: MTAC REVIEW

Iontophoresis for Joint Pain

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Evidence Conclusion: There is insufficient evidence to conclude that iontophoresis for joint pain is effective compared to the accepted alternatives, corticosteroid injection and NSAID treatment. No studies compared iontophoresis with one of these established treatments. There is some evidence that iontophoresis is not more effective than placebo treatment, although the data are limited. The highest quality study identified was an RCT comparing active iontophoresis with placebo iontophoresis in patients with epicondylitis (Nirschl). This study found a greater effect with active iontophoresis two-days after treatment, but no difference in efficacy after one-month. The study was powered to detect a 20% difference between groups. Another RCT conducted with patients with epicondylitis (Runeson) found no difference in the efficacy of active or placebo iontophoresis 3- and 6-months after treatment. Neither RCT had an intention to treat analysis, but follow-up was much higher in the Nirschl study (90% compared to 64% in the Runeson study). Statistical power was not discussed in the Runeson study. The quality of evidence for conditions other than epicondylitis was low.
Articles: The search yielded 12 articles. None of the studies compared iontophoresis to corticosteroid injection or oral medication treatment. There were four RCTs conducted with patients who had epicondylitis. Two studies compared active iontophoresis treatment to placebo treatment and were critically appraised. The two other studies had irrelevant comparison groups and were not reviewed: one compared iontophoresis with two types of active substances and one compared iontophoresis to an experimental treatment, phonophoresis. In addition, there were three controlled studies conducted among patients with other types of tendonitis. All three had weaker methodology than the placebo-controlled epicondylitis studies and were not reviewed. Two did not compare the different treatment groups in analysis and one had a sample size of only 22 patients. *The following studies were critically appraised:*
Nirschl RP, Rodin DM, Ochiai et al. Iontophoretic administration of dexamethasone sodium phosphate for acute epicondylitis. *Am J Sports Med* 2003; 31: 189-195. See Evidence Table. Runeson L, Haker E. Iontophoresis with cortisone in the treatment of lateral epicondylalgia (tennis elbow)- a double blind study. *Scand J Med Sci Sports* 2002; 12: 136-142. See Evidence Table.

The use of iontophoresis in the treatment of joint pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Medication Delivery with Iontophoresis for Temporomandibular Joint (TMJ) Dysfunction

BACKGROUND
Temporomandibular joint (TMJ) dysfunction is a common condition and involves pain, particularly in the chewing muscles and jaw joint, radiating pain in the face, neck or shoulders, painful clicking sounds in the jaw joint, and restricted jaw movement. Drug therapies for TMJ dysfunction include analgesics, minor tranquilizers or muscle relaxants at bedtime, antidepressants, injections of a local anesthetic and cortisone injections.
Iontophoresis is the use of electricity to enhance the percutaneous absorption of a drug or chemical ions. Ions in solution are transferred through the skin by passing DC electrical current between two electrodes. Iontophoresis uses a low current and patients' have little or no sensation during the procedure. Drugs used in iontophoresis should be those that ionize. Drugs used for iontophoresis to treat TMJ include lidocaine hydrochloride (a positive ion forming drug) and dexamethasone sodium phosphate (a negative ion forming drug) (Lark & Gangarosa). Iontophoresis is proposed as an alternative to local anesthetic injections for the treatment of TMJ dysfunction. Possible advantages are less discomfort than interarterial injection and fewer side effects than systemic medications.

02/13/2002: MTAC REVIEW
Iontophoresis in the Treatment of Temporomandibular Joint Syndrome
Evidence Conclusion: There is insufficient published scientific evidence on which to base conclusions about the effect of medication delivery with iontophoresis on health outcomes in patients with temporomandibular joint syndrome. Two small RCTs were reviewed, both of which may have had insufficient statistical power to detect clinically important differences between groups; neither of the study discussed statistical power calculations. Shiffman did not compare the randomized groups in analysis. Reid did not find that iontophoresis was more effective than placebo.
Articles: The search yielded eight articles. The majority were review articles/opinion pieces. There were two small randomized controlled trials (RCTs) with clinical outcomes. These two articles were critically appraised: Shiffman EL, Braun BL, Lindgren BR. Temporomandibular joint iontophoresis: A double-blind randomized clinical trial. J Orofacial Pain 1996; 10: 157-65. See Evidence Table. Reid KJ, Dionne RA, Sicard-Rosenbaum L, Lord D, Dubner RA. Evaluation of iontophoretically applied dexamethasone for painful pathologic temporomandibular joints. Oral Surg Oral Med Oral Pathol 1994; 77: 605-9. See Evidence Table.

The use of Iontophoresis in the treatment of temporomandibular joint syndrome does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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02/13/2002	12/07/2010[MDCRPC], 10/04/2011[MDCRPC], 08/07/2012[MDCRPC] ,06/04/2013[MDCRPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC] ,08/07/2018[MPC]	08/06/2013

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L35008
12/13/2017	Added home unit language

Codes

CPT: 97033

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