COVERAGE:

Iontophoresis for any medical indication is experimental or investigational.

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. 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 and possibly create potential-dependent pores in lipid bilayer membranes. It has been proposed for numerous uses, including delivering local anesthetic before skin puncture or other painful dermal procedure and local drug delivery for agents such as nonsteroidal anti-inflammatory drugs or corticosteroids for musculoskeletal inflammatory disorders. In the treatment of musculoskeletal disorders, iontophoresis is often offered in the physical medicine and rehabilitation setting. Iontophoresis has also been investigated for the treatment of hyperhidrosis of the hands and feet.

RATIONALE:

This policy is based on a 2000 TEC assessment, which evaluated 4 different indications for iontophoresis. In general, for most indications, placebo controlled studies demonstrated that iontophoretic drug delivery exceeded the effects of iontophoretic delivery of a placebo. While these studies are an important first step, they are considered insufficient to validate the efficacy of iontophoretic drug delivery compared to other methods, such as no drugs, topical applications of drugs, oral, subcutaneous, intradermal injection, etc. The side effects of iontophoresis include blanching, erythema, vesiculation, pain, tingling, and dermal burns. The TEC assessment offered the following conclusions for each of the following indications.

1. Administering local anesthetic before skin puncture or dermal laser treatment, in which the efficacy of iontophoresis was compared to local anesthetic administered via topical, intradermal, or subcutaneous routes, and to no anesthetic at all. The available comparative data on actual patient populations are derived from 2 trials that were not randomized or blinded. The results from these patient trials do not provide strong support for iontophoretic delivery of local anesthetic prior to skin puncture.
2. Treatment of musculoskeletal inflammatory disorders with nonsteroidal anti-inflammatory drugs (NSAIDs), in which drug delivery with iontophoresis was compared with other routes. The benefit of iontophoresis for local delivery on NSAIDs could be avoidance of the adverse effects of systemic administration of higher doses of these drugs and possibly equivalent or greater therapeutic effects. However, no studies compared iontophoretic delivery of an NSAID and drug delivery by a different route.

3. Treatment of musculoskeletal inflammatory disorders with corticosteroids in which drug delivery with iontophoresis is compared to other routes, including topical, oral, intramuscular, or intra-articular. The benefit of iontophoresis for local drug delivery could be avoidance of the adverse effects of systemic administration of higher doses of these drugs and possibly equivalent or greater therapeutic effects. However, no study compared iontophoretic delivery of steroids with drug delivery by a different route.

4. Various miscellaneous indications for iontophoresis were investigated, including post-herpetic neuralgia, herpetic orolabialis, postoperative pain, ear burns, persistent tinnitus, pediatric otitis media, Peyronie’s disease, venous stasis ulcers, dyshidrotic hand eczema, and calcifying tendonitis of the shoulder. In addition to the lack of adequate placebo studies to show whether the effects of iontophoretic delivery exceed placebo effects evidence is lacking from studies making the critical comparison between iontophoretic drug delivery and drug delivery by another route.

PRICING:

None

REFERENCES:

- Van der Geest R, van Laar T, Gubbens-Strigge JM, Bodde HE, Hanhof, Blue Cross and Blue Shield of Texas, a Division of Health Care Service Corporation, a Mutual Legal Reserve Company* Southwest Texas HMO, Inc.* d/b/a HMO Blue® Texas * Independent Licensees of the Blue Cross and Blue Shield Association


• "Iontophoresis for Medical Indications." BCBSTX TEC Assessment Program, Volume 15, No. 20: March 2001.

• "Iontophoresis as a Technique for Drug Delivery." Blue Cross Blue Shield Association Medical Policy (5/31/01) 8.03.14.

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.