

Medical Policy Manual

Topic: Galvanic Stimulation

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Section: DME

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Galvanic stimulation is comprised of unidirectional current flow through two electrodes, one negative and one positive, placed at strategic locations on the skin. Galvanic stimulation is proposed to work by facilitating ion movement under the skin, promoting circulation near the negative electrode, while reducing circulation near the positive electrode. It is theorized that these changes in circulation promote wound healing and reduce edema and inflammation, therefore also decreasing pain associated with these conditions.

MEDICAL POLICY CRITERIA

Galvanic stimulation devices are considered **investigational** for the treatment of all indications, including but not limited to pain.

SCIENTIFIC EVIDENCE

The principal outcomes associated with treatment of pain due to any cause may include: relief of pain, improved functional level, and return to work. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore, data from adequately powered, blinded, randomized

controlled trials (RCTs) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from an electrical stimulation device provides a significant advantage over the placebo.

Treatment with an electrical stimulation device must also be evaluated in general groups of patients against the existing standard of care for the condition being treated. For example, in patients with pain symptoms, treatment with an electrical stimulation device should be compared with other forms of conservative therapy such as splinting, rest, non-steroidal anti-inflammatory medications, physical therapy, or steroid injection.

Literature Appraisal

There is no published evidence on the use of galvanic stimulation for edema reduction or wound healing. Instead, the focus of published literature to date has been on the use of galvanic stimulation for pain reduction. There is one Cochrane review of galvanic stimulation for the treatment of neck pain, but in general the evidence is limited in both quality and quantity.

Technology Assessments/Systematic Reviews

The 2009 Cochrane review of electrotherapy for neck pain included a review of galvanic stimulation.^[1] Although the review found that the published literature on galvanic stimulation appeared promising, it concluded that the evidence was of very low quality and that more studies were needed to reliably establish effectiveness.

Randomized Controlled Trials (RCTs)

Current evidence from randomized controlled trials regarding the benefits of galvanic stimulation is limited to two small studies.

Krewer and colleagues conducted a randomized observer-blinded cross-over trial to evaluate the after-effects of galvanic vestibular stimulation (GVS), machine-supported gait training with the Lokomat, and physiotherapy with visual feedback components (PT-vf) on pusher behavior in 25 stroke patients (15 pushers, 10 non-pushers). The scale for conservative pushing (SCP) and Burke lateropulsion scale (BLS) were used to evaluate patient pushing behavior, both before and after a single session of each intervention. The authors reported no significant effect was observed on either scale with GVS.^[2]

Cevette and colleagues evaluated the effect of GVS on simulator sickness (SS) during flight simulations in 21 normal subjects.^[3] In a baseline simulation, GVS dose response predictions were formulated for each subject based on perceptions of roll, pitch and yaw simulations. These data were then used to create a stimulation algorithm in order to synchronize visual and GVS-induced vestibular sensation. Subjects were then randomly exposed to the designed stimulation or nothing during flight simulation. Patients were then given a SS checklist after each session to evaluate sickness. Authors reported the overall SS score for gastrointestinal, central, and peripheral categories were 17%, 22.4%, and 20% for the control group and 6.3%, 20%, and 8% for the treatment group, respectively. Although there is reported improvement in SS with GVS treatment, neither patients nor researchers were blinded to stimulation, allowing for treatment bias. In addition, self-reporting bias was not properly controlled for as SS was evaluated only by a self-administered patient questionnaire.

Clinical Practice Guidelines

There are no evidence-based clinical practice guidelines that recommend the use of galvanic stimulation devices for the treatment of pain.

Summary

Based on the lack of published long-term objective outcomes from well-designed, well-executed randomized controlled clinical trials, conclusions cannot be reached concerning the effectiveness of galvanic stimulation as a treatment of pain or any other condition. Therefore, galvanic stimulation is considered investigational for all indications. Larger, randomized, placebo-controlled trials of longer duration are needed to evaluate the effectiveness of galvanic stimulation devices in improving pain and function and to determine whether galvanic stimulation offers any additional benefit compared with sham treatment or other standard treatments.

REFERENCES

1. Brosseau, LU, Pelland, LU, Casimiro, LY, Robinson, VI, Tugwell, PE, Wells, GE. Electrical stimulation for the treatment of rheumatoid arthritis. *Cochrane Database Syst Rev*. 2002(2):CD003687. PMID: 12076504
2. Krewer, C, Riess, K, Bergmann, J, Muller, F, Jahn, K, Koenig, E. Immediate effectiveness of single-session therapeutic interventions in pusher behaviour. *Gait Posture*. 2013 Feb;37(2):246-50. PMID: 22889929
3. Cevette, MJ, Stepanek, J, Cocco, D, et al. Oculo-vestibular recoupling using galvanic vestibular stimulation to mitigate simulator sickness. *Aviat Space Environ Med*. 2012 Jun;83(6):549-55. PMID: 22764608

CROSS REFERENCES

[Electrical Stimulation Devices Index](#), Durable Medical Equipment, Policy No. 83

CODES	NUMBER	DESCRIPTION
CPT	None	
HCPCS	E1399	Durable medical equipment, miscellaneous