Galvanic Stimulation

Effective: February 1, 2024

Next Review: November 2024
Last Review: December 2023

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 describes unidirectional electrical current between two electrodes placed on the skin. It has been proposed as a treatment for various conditions, including but not limited to impaired perfusion or circulation, inflammation, pain, and/or symptoms from vestibular nerve disorders (e.g. balance and nausea).

MEDICAL POLICY CRITERIA

Galvanic stimulation is considered **investigational** for the treatment of all indications, including but not limited to impaired perfusion or circulation, inflammation, pain, and/or symptoms from vestibular nerve disorders.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

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 or perfusion promote wound healing, reduce edema and inflammation, and decrease pain. Finally, galvanic stimulation is also proposed to work on the vestibular nerve to help with balance and nausea.

EVIDENCE SUMMARY

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.

SYSTEMATIC REVIEWS

Pires (2022) published a systematic review to identify evidence in the scientific literature about the clinical applications of galvanic vestibular stimulation.[1] The articles describing the applications of galvanic vestibular stimulation were extracted from PubMed, Web of Science, MEDLINE, Scopus, LILACS and SciELO databases. The search strategy resulted in the initial selection of 994 articles; the reading of titles and abstracts was accomplished in 470 articles and the complete reading in 23 articles. Clinical applications of galvanic vestibular stimulation included Ménière's disease, vestibular neuritis, bilateral vestibular disorders, vestibular schwannoma, Parkinson's disease, ischemic central lesions, motor myelopathies, anxiety disorders, cognition and memory.

Parkinson’s disease patients develop postural imbalance and tend to fall. A systematic review by Mahmud (2022) reported that after reviewing 223 studies and evaluating 14, five studies qualified for meta-analysis.[2] Among 40 patients in five studies (range n = 5 to 13) they found that GVS has a favorable effect on postural balance in patients with Parkinson’s disease. The authors also commented that “…due to limited literature and inconsistent methodologies, this favorable effect must be interpreted with caution.”

McLaren (2022) published a systematic review and meta-analysis to investigate the evidence for noisy galvanic vestibular stimulation (nGVS) as a modality to improve postural control in people with bilateral vestibulopathy (BVP).[3] From the systematic search, seven studies were met the criteria and five were chosen for the meta-analysis. A moderate effect in favor of nGVS improving postural control during standing and walking was found [pooled SMD = 0.47 (95% CI 0.25, 0.7)]. nGVS-mediated improvements in postural control were most evident in observations of reduced sway velocity when standing on a firm surface with eyes closed, and in the reduced variability of gait parameters, particularly those measuring lateral stability. The authors commented that “Further research is warranted investigating additional circumstances in which nGVS improves postural control, including investigating the residual, and sustained effects of nGVS.”

Williams (2017) published a systematic review (SR) evaluating non-invasive treatments for peripheral artery disease, which included intermittent pneumatic compression, electrical nerve (NMES), muscle stimulators, and galvanic electrical stimulation.[4] Thirty-one papers were reviewed, two of which evaluated the impact of galvanic electrical stimulation on impaired perfusion and microvascular insufficiency or diabetic foot ulcers. The authors stated galvanic stimulation is not recommended.

In 2013 Cochrane updated their 2009 Cochrane review of electrotherapy for neck pain included a review of galvanic stimulation.[5] The original review found that the published literature on galvanic stimulation appeared promising; however, it concluded that the evidence was of very low quality and that more studies were needed to reliably establish effectiveness. In the updated review, authors concluded very low quality evidence showed that modulated galvanic stimulation was no more effective than placebo.[6]

RANDOMIZED CONTROLLED TRIALS

Gutkovich (2021) publish a single blind, RCT in which 30 seasickness susceptible subjects were enrolled after at least six months of regular sailing.[7] The treatment group underwent galvanic vestibular stimulation (GVS) coupled with inverse phase rotatory chair impulse in sinusoidal harmonic acceleration protocol. The control group underwent a sham procedure. All subjects performed repeated velocity step tests to determine the vestibular time constant (Tc) and completed a seasickness questionnaire. The GVS rotatory chair procedure decreased the prevalence of severe seasickness. The number of motion sickness clinic visits and anti-motion sickness drug consumption were reduced in the treatment group three-month post intervention as compared to control. In addition, there was significant reduction of Tc in the treatment group.

Külünkoğlu (2021) published the result of a randomized controlled trial comparing splinting, exercise, and electrotherapy in the treatment of patients with hallux valgus (HV).[8] Sixty women (120 feet) with bilateral HV deformity were randomly assigned to an HV night splint group, an exercise group, or a high-voltage galvanic stimulation (HVPGS) group. In the stimulation group, HVPGS was applied over three weekly sessions for four weeks. Outcomes were assessed at three-months post-treatment and consisted of angular degrees (hallux interphalangeal angle (HIPA), HV angle (HVA), and intermetatarsal angle (IMA)), as well as foot-specific quality of life assessed using the Manchester-Oxford Foot Questionnaire. While significant changes in HIPA, HVA, and IMA angles and quality of life outcome measures were found for all groups compared to baseline ($p \leq 0.001$), significantly more improvement in the HIPA and IMA angles, and MOFQ-Pain subscale scores were found in the splinting group than in the other two groups ($p < 0.05$).

Volkening (2018) evaluated the effects of bipolar galvanic vestibular stimulation (GVS) on spatial neglect, extinction and verticality perception in 24 stroke patients.[9] The GVS group received treatments of 1.5mA for 20 minutes with cathodes on the left and right mastoid, while the sham group received treatments of only 30 seconds with cathodes on the left mastoid. There was a total of 10-12 treatments, one daily five days per week, for both groups, and all patients additionally received a standard therapy of smooth pursuit eye movement training. The outcomes were Neglect test, visuo-tactile search task, subjective visual and tactile vertical, and these were assessed at baseline, immediately after treatment, and at two- and four-week follow-up visits. Neither group showed significant improvements in neglect symptoms.

Krewer (2013) conducted a randomized observer-blinded cross-over trial to evaluate the after-effects of 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).[10] 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.

Cevette (2012) evaluated the effect of GVS on simulator sickness (SS) during flight simulations in 21 normal subjects.[11] 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.

PRACTICE GUIDELINE SUMMARY

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

SUMMARY

There is not enough research to show if or how well galvanic stimulation works for any indication, including but not limited to impaired perfusion or circulation, inflammation, pain, and/or symptoms from vestibular nerve disorders (e.g. balance and nausea). No clinical guidelines based on research recommend the use of galvanic stimulation. Therefore, galvanic stimulation is considered investigational for all indications.

REFERENCES

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CODES

Codes	Number	Description
CPT	None	
HCPCS	E1399	Durable medical equipment, miscellaneous

Date of Origin: *January 2012*