Clinical Practice Guideline: **H-Wave® Electrical Stimulation**

Date of Implementation: **February 18, 2016**

Product: **Specialty**

GUIDELINES

American Specialty Health – Specialty (ASH) considers the use of H-wave electrical stimulation (97014 and E0745) unproven for all indications, including but not limited to:

- Treatment of pain; including but not limited to chronic pain due to ischemia and diabetic peripheral neuropathy, and other chronic pain;
- Wound healing or to accelerate healing in general;
- Post-operative treatment to improve function and/or range of motion;
- Reduction of edema.

CPT®/HCPCS Code and Descriptions

CPT®/HCPCS Code	CPT®/HCPCS Code Description
97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)*
E0745	Neuromuscular stimulator, electronic shock unit**

* **CPT®** code 97014 is a nonspecific **CPT®** code and thus does not distinguish H-wave stimulation from other forms of electrical stimulation.

**HCPCS code E0745 use is inclusive of electrical stimulation prescribed for use in the home, rental, or purchase of H-wave devices.

DESCRIPTION/BACKGROUND

H-wave® device stimulation (HWDS) is a distinct form of electrical stimulation. H-wave electrical stimulation has been evaluated primarily as a treatment of pain related to a variety of etiologies, such as diabetic neuropathy, muscle sprains, temporomandibular joint dysfunctions, or reflex sympathetic dystrophy (RSD). H-wave stimulation has also been used to accelerate healing of wounds such as diabetic ulcers and to improve range of motion and function after orthopedic surgery. Both office-based and home models of the H-wave device are available. H-wave stimulation is a form of electrical stimulation that differs from other forms of electrical stimulation, such as transcutaneous electrical nerve stimulation

(TENS), in terms of its wave form. While H-wave stimulation may be performed by physicians, physiatrists, chiropractors, or podiatrists, H-wave® devices are also available for home use. It is important to note that H-wave® device electrical stimulation must be distinguished from the H-waves that are a component of electromyography.

REGULATORY STATUS

The H-wave® device is U.S. Food and Drug Administration (FDA) approved for medical purposes that involve repeated muscle contractions. Uses of the device not cleared by the FDA include, but are not limited to, treatment of diabetic neuropathy and wound healing. In 1992, the H-Wave® muscle stimulator (Electronic Waveform Lab, Huntington Beach, CA) was cleared for marketing by the FDA through the 510(k) process. More than 100 electrical stimulation devices have received 510(k) approval from the FDA. Marketing clearance via the 510(k) process does not require data regarding clinical efficacy. The FDA classified H-wave® stimulation devices as "powered muscle stimulators." As a class, the FDA describes these devices as being "intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area." According to the FDA, manufacturers may make the following claims regarding the effect of the device: "1) relaxation of muscle spasms; 2) prevention or retardation of disuse atrophy; 3) increasing local blood circulation; 4) muscle re-education; 5) immediate post-surgical stimulation of calf muscles to prevent venous thrombosis; and, 6) maintaining or increasing range of motion." In 1997, the FDA sent a warning letter to the distributors of the device which noted that upon review of promotional materials, H-Wave® was being promoted for intended uses that have not been cleared by the FDA. Additional violations were identified as well.

The H-wave® device is an electrostimulation device that has been used to reduce pain and swelling associated with a variety of diseases and conditions. The hypothesis that the H-Wave device (Electronic Waveform Lab, Inc., Huntington Beach, CA), a small-diameter fiber stimulator, is a paradigm shift of electrotherapeutic treatment of pain associated with human neuropathies and sports injuries is based on a number of its properties. H-wave stimulation delivers electrical stimulation in the form of milliamperage. H-wave stimulation is intended to emulate the H waveform found in nerve signals (Hoffman Reflex) and therefore would enable greater and deeper penetration of a low frequency current, while using significantly less power than other machines. This allegedly makes H-Wave stimulation much safer, less painful and more effective than other forms of electrotherapy to date. The H-wave signal is a bipolar, exponential decaying waveform that supposedly overcomes the disadvantages of other electrotherapy machines. It allows the practitioner to apply 2 treatments at the same time: (i) low-frequency muscle stimulation and (ii) high-frequency deep analgesic pain control (a 'TENS' effect). According to Blum et al. (2008), the primary effect of H-Wave device stimulation (HWDS) is the stimulation of 'red-slow-twitch' skeletal muscle fibers. Blum et al. (2008) propose, based on the unique waveform, that the H-Wave ® device specifically and directly stimulates the small smooth

muscle fibers within the lymphatic vessels ultimately leading to fluid shifts and reduced edema. In unpublished rat studies, it has been observed that HWDS induces protein clearance. The H-Wave® device was designed to stimulate an ultra-low frequency (1-2 Hz), low tension, non-tetanizing, and non-fatiguing contraction, which closely mimics voluntary or natural muscle contractions. The H-Wave® device can stimulate small fibers due in part to its exponentially decaying waveform and constant current generator activity. The main advantage of these technologies over currently applied electrical stimulators (e.g., transcutaneous electrical nerve stimulator [TENS], interferential [IF], neuromuscular electrical stimulation [NMES], high-volt galvanic) is that H-Wave's® small fiber contraction does not trigger an activation of the motor nerves of the large white muscle fibers or the sensory delta and C pain nerve fibers, thus eliminating the negative and painful effects of tetanizing fatigue, which reduces transcapillary fluid shifts. Another function of the H-Wave® device is an anesthetic effect on pain conditions, unlike a TENS unit which in the short term activates a sensory overload effect (gate theory) to stop pain signals from reaching the thalamic region of the brain. When the H-Wave® device is used at high frequency (60 Hz), authors propose it acts intrinsically on the nerve to deactivate the sodium pump within the nerve fiber, leading to a long-lasting anesthetic/analgesic effect due to an accumulative postsynaptic depression. Moreover, they suggest that HWDS produces a nitric oxide (NO)-dependent enhancement of microcirculation and angiogenesis in rats. Thus, Blum et al. (2008) hypothesize that because of these innate properties of the H-Wave® device, it may provide a paradigm shift for the treatment of both short- and long-term inflammatory conditions associated with pain due to sports injuries. It is very important to note that Blum and several co-investigators are consultants to the device manufacturer.

EVIDENCE REVIEW

Pain Treatment

In 2008, Blum and colleagues published a meta-analysis of studies evaluating the H-Wave® device for treatment of chronic soft tissue inflammation and neuropathic pain. Five studies, 2 RCTs and 3 observational studies, met inclusion criteria. Four of the studies measured pain reduction. In a pooled analysis of data from these 4 studies (treatment groups only), the mean weighted effect size was 0.59. Two studies reported the effect of the H-Wave® device on pain mediation use; the mean weighted effect size was 0.56. A limitation of this analysis was that the authors did not use data from patients in the control or comparison groups; thus, the incremental effect of the H-Wave device beyond that of a comparison intervention cannot be determined. A critique of this systematic evidence review by the Centre for Reviews and Dissemination (2009) concluded that "it is not possible to determine whether the results of this review are reliable" given its significant methodologic limitations. In particular, very limited details of the included studies were given in the review; in particular it was unclear which studies were randomized, no control interventions were detailed, and there were insufficient details on the outcome measures used. Although a validity assessment was performed, the results were not presented.

"Given these omissions, it is difficult to assess either the internal or external validity of the results." The CRD noted that the authors of the systematic evidence review used meta-analysis to combine the results, but different measures of effect appeared to be combined in a single effect size. Insufficient details on the outcome measures used in the included studies meant that it was not possible to determine if this was appropriate or not. The CRD critique noted that, in addition to four authors of the systematic evidence review being independent consultants for Electronic Waveform Lab (the makers of the H-Wave® device), 2 authors were members of the research groups responsible for conducting the primary studies. The five studies identified by the systematic review for the meta-analysis were published by two research groups; Kumar and colleagues published three studies and the other two were published by Blum and colleagues. In 1997, Kumar and Marshall published a randomized controlled trial comparing active H-wave electrical stimulation with sham stimulation for treatment of diabetic peripheral neuropathy. Thirty-one patients with type 2 diabetes and painful peripheral neuropathy in both lower extremities lasting at least 2 months were selected as subjects. Patients were excluded if they had vascular insufficiency of the legs or feet, or specified cardiac conditions. Patients were randomly assigned to the active group (n =18) or the sham group (n =13). Both groups were instructed to use their devices 30 minutes daily for 4 weeks. The device used in the sham group had inactive electrodes. Outcomes were assessed using a pain-grading scale. Both groups experienced significant declines in pain with the active group having a significantly lower pain score than the sham group post-treatment. The authors reported that H-wave treated patients exhibited greater symptomatic relief than their sham-treated counterparts. This study did not state whether patients and/or investigators were blinded and did not state whether any patients withdrew from the study.

Another randomized study published by Kumar and colleagues in 1998 compared active H-wave electrical stimulation with sham stimulation among patients treated initially with a tricyclic antidepressant for their neuropathy. Twenty-six patients with type 2 diabetes and painful peripheral neuropathy persisting for 2 months or more were selected for the study. Exclusion criteria were similar to those used in the earlier study. Amitriptyline was administered for 4 weeks initially, and those who had a partial response or no response were later randomized to the 2 groups. After excluding 3 amitriptyline responders, the active stimulation group included 14 patients and the sham stimulation included 9 patients. Sham devices had inactive output terminals. Stimulation therapy lasted 12 weeks, and final outcome assessment was conducted by an investigator blinded to group assignment 4 weeks after the end of treatment. As in the earlier study, mean pain scores in both groups improved significantly, but the difference between groups after treatment significantly favored active H-wave stimulation. It is unclear if patients were blinded to the type of device, and the report does not note whether withdrawals from the study occurred. Moreover, other studies have shown that H-wave stimulation may be a useful adjunctive modality when combined with pharmacotherapy (e.g., amitriptyline) to augment symptomatic relief in patients with diabetic peripheral neuropathy (Julka et al., 1998).

Two observational studies on the H-Wave device were published by Blum and colleagues (2006) and consisted of patient's responses to 3 of 10 questions on a manufacturer's customer service questionnaire (i.e., warranty registration card). In the larger of the 2 reports, 80% of 8,498 patients with chronic soft-tissue injury and neuropathic pain who were given the H-Wave® device completed the questionnaire. The answers were compared with an expected placebo response of 37% improvement. Following an average 87 days of use, 65% of respondents reported a decrease the amount of medication needed, 79% reported an increase in function and activity, and 78% of respondents reported an improvement in pain of 25% or greater. On the other hand, H-wave stimulators have not been shown to be effective in reducing pain from causes other than chronic diabetic peripheral neuropathy, or in reducing edema or swelling. In particular, H-wave stimulation has not been demonstrated to be effective in treating chronic pain due to ischemia. In the study by Kumar and Marshall (1997), patients with significant peripheral vascular disease were excluded from the trial. Furthermore, in a randomized controlled study (n = 112), McDowell et al. (1995) reported that H-wave stimulation was not effective in reducing experimental ischemic pain.

Allen et al. (2023) compared the relative effects of various forms of electric stimulation (ES) on functional and pain outcomes. Authors report that varying forms of ES have markedly different technical parameters, applications, and indications, based on clinically meaningful impact on pain perception, function improvement, and medication reduction. Authors explain that there is limited quality evidence for most forms of ES, although there are several notable exceptions for treatment of specific indications. Neuromuscular electrical stimulation (NMES) has well-demonstrated beneficial effects for rehabilitation of selective spinal cord injured (SCI), post-stroke, and debilitated inpatients. Functional electrical stimulation (FES) has similarly shown effectiveness in rehabilitation of some stroke, SCI, and foot drop outpatients. H-Wave® device stimulation (HWDS) has moderate supportive evidence for treatment of acute and refractory chronic pain, consistently demonstrating improvements in function and pain measures across diverse populations. Interestingly, transcutaneous electrical nerve stimulation (TENS), the most widely used form of ES, demonstrated insignificant or very low levels of pain and functional improvement. Authors concluded that ten of 13 reviewed forms of ES have only limited quality evidence for clinically significant reduction of pain or improvement of function across different patient populations. NMES and FES have reasonably demonstrated effectiveness, albeit for specific clinical rehabilitation indications. HWDS was associated with the most clinically significant outcomes, in terms of functional improvement combined with reduction of pain and medication use. More rigorous long-term clinical trials are needed to further validate appropriate use and specific indications for most forms of ES. Limitations of this study include that data was collected by the device manufacturer where there is a potential conflict of interest.

Norwood et al. (2024) conducted a retrospective independent statistical analysis on Patient-Reported Outcome Measures (PROMs) data for users of H-Wave® device stimulation (HWDS) for chronic low back pain (cLBP) collected by the device manufacturer over a period of 4 years. Final surveys for 34,192 pain management patients were filtered for pain chronicity limited to 3-24 months and device use of 22-365 days, resulting in 11,503 patients with "all diagnoses"; this number was then reduced to 2711 patients with nonspecific cLBP, sprain, or strain. Reported pain was reduced by 3.12 points (0-10 pain scale), with significant (≥ 20%) relief in 85.28%. Function/activities of daily living (ADL) improved in 96.36%, while improved work performance was reported in 81.61%. Medication use decreased or stopped in 64.41% and sleep improved in 59.76%. Over 96% reported having expectations met or exceeded, service satisfaction, and confidence in device use, while no adverse events were reported. Subgroup analyses found positive associations with longer duration of device use, home exercise participation, and working, whereas older age and longer pain chronicity resulted in reduced benefit. Similar analysis of the larger all-diagnoses cohort demonstrated near-equivalent positive outcomes. Authors concluded that outcomes directly reported by cLBP HWDS patients demonstrated profound positive effects on function and ADL, robust improvement in pain perception, and additional benefits like decreased medication use, better sleep, and improved work performance, representing compelling new evidence of treatment efficacy. Limitations of this study include that data was collected by the device manufacturer where there is a potential conflict of interest.

Wound Healing

The only published study identified in literature searches was a case report from 2010 describing outcomes in 3 patients with chronic diabetic leg ulcers who used the H-Wave® device (Blum et al., 2010).

Post-Operative Rehabilitation

In 2009, Blum and colleagues published a small double-blind placebo-controlled randomized trial evaluating home use of the H-Wave® device for improving range of motion and muscle strength after rotator cuff reconstruction surgery. Electrode placement for the H-Wave® device was done during the surgical procedure. After surgery, patients were provided with an active H-wave® device (n =12) or sham device (n =10) and were instructed to use the device for one hour twice a day for 90 days. Individuals in the sham group were told not to expect any sensation from the device. Both groups also received standard physical therapy. At follow-up, range of motion of the involved extremity was compared to that of the uninvolved extremity. At the 90-day post-operative examination, patients in the H-wave group had significantly less loss of external rotation of the involved extremity (mean loss of 11.7 degrees) compared to the placebo group (mean loss of 21.7 degrees). Moreover, there was a statistically significant difference in loss of internal rotation, a mean loss of 13.3 degrees in the H-wave group and a mean loss of 23.3 degrees in the placebo group. There were no statistically significant differences between groups in

post-operative strength. The authors also stated that there was no statistically significant difference on any of the other 4 range of motion variables. The study did not assess change in functional status or capacity.

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