Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 3/1/24**
(See policy history boxes for previous effective dates)

Title: H-Wave Stimulation

Description/Background

H-wave stimulation has been proposed for the treatment of pain related to a variety of etiologies, including diabetic neuropathy, muscle sprains, temporomandibular joint dysfunctions, and reflex sympathetic dystrophy. H-wave stimulation has also been used to attempt to accelerate healing of certain types of wounds, such as diabetic ulcers and to improve range of motion and function after orthopedic surgery.

H-wave stimulation is a distinct form of electrical stimulation that differs from other forms of electrical stimulation, such as transcutaneous electrical nerve stimulation (TENS), in terms of its waveform. 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 in theory adds 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. The H-wave signal is a bipolar, exponential decaying waveform that supposedly overcomes the disadvantages of other electrotherapy machines. It allows the therapist to apply 2 treatments at the same time: (1) low-frequency muscle stimulation and (2) high-frequency deep analgesic pain control (a "TENS" effect). H-wave devices are also available for home use.

H-wave electrical stimulation must be distinguished from the H-waves that are a component of electromyography. The RS-4i® Sequential Stimulator was developed by RS Medical and is a form of H-wave electrical current therapy (electrotherapy). The RS-4i Sequential Stimulator is proposed to treatment acute and chronic pain, to prevent muscle atrophy, and to rehabilitate injured muscle. The RS-4i® has multiple delivery modes and can deliver interferential stimulation as well as standard electrical muscle stimulation. The system consists of a hardware and software package including a plastic operating unit with keypad and LCD display, output cables, electrode pads and AC adapter.

During a typical RS-4i® sequential treatment session, electrode pads are placed according to a prescribed configuration. The first phase of treatment uses interferential electrical current to provide pain relief. The second phase is intended to restore muscle function through administering standard electrical muscle stimulation. According to the manufacturer, sequential stimulation is different from another well-known form of electrotherapy known as TENS (transcutaneous electrical nerve stimulation), in that it is proposed to provide longer-lasting pain relief and have curative value.

Regulatory Status

A variety of devices may be used for H-wave stimulation. In general, the U.S. Food and Drug Administration (FDA) has classified them as “powered muscle stimulators.” As a class, the FDA describes these devices as “an electronically powered device intended for medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area.” Product code: IPF

Medical Policy Statement

The use of H-wave stimulation is experimental/investigational for all indications, including but not limited to treatment of pain (including diabetic peripheral neuropathic pain), wound healing and postoperative treatment to improve function and/or range of motion. Its use has not been scientifically demonstrated to result in improved patient outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

A4556	A4557	E1399	97014	97032

Rationale

Most of the studies identified in searches evaluated H-wave stimulation for treating pain. As with other technologies intended to relieve pain, measurement of placebo effects is important and therefore the searches focused on placebo (sham)-controlled studies. Studies were also

identified on H-wave stimulation for wound healing and post-surgical rehabilitation but not for other proposed clinical applications of the technology.

Pain treatment

Blum et al (2008) published a meta-analysis of studies evaluating the H-Wave device for treatment of chronic soft tissue inflammation and neuropathic pain. Five studies, 2 randomized controlled trials (RCTs) and 3 observational studies, met inclusion criteria. Four of the studies used a measure of 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. (An effect size of 0.5 is considered a moderate effect and of 0.80 is considered a large effect.) A limitation of this analysis was that the authors did not use data from individuals in the control or comparison groups; thus, the incremental effect of the H-Wave device beyond that of a comparison intervention cannot be determined.

The 5 studies identified by the systematic review for the meta-analysis were published by 2 research groups; Kumar et al published 3 studies and the other 2 were published by Blum et al. Blum and several co-investigators are consultants to the device manufacturer. Descriptions of the individual published studies are included below.

A critique of the 2008 Blum systematic evidence review by the Centre for Reviews and Dissemination (CRD, 2009) concluded, "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-analyses 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 4 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.

Kumar et al (1997) published an RCT comparing active H-wave electrical stimulation with sham stimulation for treatment of diabetic peripheral neuropathy. The authors selected 31 patients with type 2 diabetes and painful peripheral neuropathy in both lower extremities lasting at least 2 months. 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 (ranging from 0 to 5). Both groups experienced significant declines in pain, and the post-treatment mean grade for the active group was significantly lower than the mean grade for the sham group. This study did not state whether the subjects and/or investigators were blinded and it did not state whether any individuals withdrew from the study.

Another randomized study published by Kumar et al (1998) compared active H-wave electrical stimulation with sham stimulation among individuals treated initially with a tricyclic antidepressant. The authors enrolled 26 patients with type 2 diabetes and painful peripheral neuropathy persisting for 2 months or more. 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 randomly assigned 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 the 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 grade in both groups improved significantly, but the difference between groups after treatment significantly favored active H-wave stimulation. Results on an analogue scale were similar. It is unclear whether subjects were blinded to the type of device, and the report does not note whether withdrawals from the study occurred. A later report from this research group described a case series of 34 individuals who continued H-Wave electrical stimulation for more than 1 year and achieved a 44% reduction in symptoms.

Two observational studies on the H-Wave device were published by Blum et al (2006, 2010) and consisted of subjects' 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 individuals 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 in 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.

Wound healing

Blum et al (2010) is the only published study (case report) that was identified in literature which described outcomes in 3 patients with chronic diabetic leg ulcers who used the H-Wave device.

Post-operative rehabilitation

Blum et al (2009) 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, subjects were provided with an active H-wave device (n=12) or sham device (n=10) and were instructed to use the device for 1 hour twice daily 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 postoperative 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), p=0.007. Moreover, there was a statistically significant difference in 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, p=0.006. There were no statistically significant differences between groups in postoperative 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.

SUMMARY OF EVIDENCE

Two small, controlled trials are insufficient to permit conclusions about the effectiveness of H-wave electrical stimulation as a pain treatment. Additional sham-controlled studies are needed from non-biased investigators, preferably studies that are clearly blinded, specify the handling of any withdrawals and provide long-term, comparative follow-up data. One small RCT represents insufficient evidence on the effectiveness of H-wave simulation for improving strength and function after rotator cuff surgery. No comparative studies have been published evaluating H-wave stimulation to accelerate wound healing. In addition, no studies were identified that evaluated H-wave stimulation for any clinical application other than those described above. The evidence is insufficient to determine that H-wave stimulation improved overall health outcomes.

Ongoing and Unpublished Clinical Trials

A search on ClinicalTrials.gov did not produce any clinical trials that might influence this policy.

Supplemental Information

American College of Occupational and Environmental Medicine (ACOEM)

Three evidence-based clinical practice guidelines (2007, 2008, 2011) included high- to moderate-quality randomized controlled clinical trials or crossover trials. ACOEM specifically recommended against H-wave stimulation for treatment of acute and chronic pain, including all of the following:

- Complex regional pain syndrome
- Neuropathic pain (insufficient evidence)
- Trigger points/myofascial pain
- Chronic persistent pain
- Chronic low back pain
- Acute low back pain
- Subacute low back pain
- Radicular pain syndromes

The ACOEM updated its guidelines (2020) to indicate that no quality studies evaluating H-Wave Device (Electronic Waveform Lab, Inc, Huntington Beach, CA) stimulation for the treatment of acute, subacute, or chronic LBP or radicular pain syndromes have been identified. Therefore, There is no recommendation (Low Confidence [I]) for or against H-Wave Device stimulation therapy.

American Psychological Association

The American Psychological Association guidelines for the treatment of depression (2019) do not mention the use of H-wave stimulation as a treatment modality.

Government Regulations
National:

National Coverage Determination (NCD) for Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds. Pub: 100-3; Manual Section number: 270.1; Version: 3. Implementation date: 7/6/04

Indications and Limitations of Coverage

A. Nationally Covered Indications

The use of ES and electromagnetic therapy for the treatment of wounds are considered adjunctive therapies and will only be covered for chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers. Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence. ES or electromagnetic therapy will be covered only after appropriate standard wound therapy has been tried for at least 30 days and there are no measurable signs of improved healing. This 30-day period may begin while the wound is acute.

Standard wound care includes: optimization of nutritional status, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, and necessary treatment to resolve any infection that may be present. Standard wound care based on the specific type of wound includes: frequent repositioning of a patient with pressure ulcers (usually every 2 hours), offloading of pressure and good glucose control for diabetic ulcers, establishment of adequate circulation for arterial ulcers, and the use of a compression system for patients with venous ulcers.

Measurable signs of improved healing include a decrease in wound size (either surface area or volume), decrease in amount of exudates, and decrease in amount of necrotic tissue. ES or electromagnetic therapy must be discontinued when the wound demonstrates 100% epithelialized wound bed.

ES and electromagnetic therapy services can only be covered when performed by a physician, physical therapist, or incident to a physician service. Evaluation of the wound is an integral part of wound therapy. When a physician, physical therapist, or a clinician incident to a physician, performs ES or electromagnetic therapy, the practitioner must evaluate the wound and contact the treating physician if the wound worsens. If ES or electromagnetic therapy is being used, wounds must be evaluated at least monthly by the treating physician.

B. Nationally Non-Covered Indications

- ES and electromagnetic therapy will not be covered as an initial treatment modality.
- Continued treatment with ES or electromagnetic therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.
- Unsupervised use of ES or electromagnetic therapy for wound therapy will not be covered, as this use has not been found to be medically reasonable and necessary.

C. Other

All other uses of ES and electromagnetic therapy not otherwise specified for the treatment of wounds remain at local Medicare Administrative Contractor discretion.

National Coverage Determination (NCD) for Treatment of Motor Function Disorders with Electric Nerve Stimulation. Pub: 100-3; Manual Section Number: 160-2; Version: 2. Implementation date: 4/1/03

Indications and Limitations of Coverage
Where electric nerve stimulation is employed to treat motor function disorders, no reimbursement may be made for the stimulator or for the services related to its implantation since this treatment cannot be considered reasonable and necessary.

Local:

There is no local coverage determination (LCD) for this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Interferential Stimulation (IFS) (Sympathetic Therapy)
- Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)
- Percutaneous Tibial Nerve Stimulation
- Peripheral Subcutaneous Field Stimulation and Peripheral Nerve Stimulation
- Transcutaneous Electrical Modulation Pain Reprocessing (Scrambler Therapy)

References

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3. American College of Occupational and Environmental Medicine. Shoulder disorders. Occupational medicine practice guidelines. Evaluation and management of common health problems and functional recovery in workers. 3rd ed. Elk Grove Village (IL): *ACOEM*; 2011. p. 1-297.
4. American Psychological Association. APA Clinical Practice Guideline for the Treatment of Depression across Three Age Cohorts. 2019. https://www.apa.org/depression-guideline/guideline.pdf. Accessed September 27, 2023.
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11. Hegmann, KT, Travis R, Gunnar BJ, et al. ACOEM Guidelines: Non-Invasive and Minimally Invasive Management of Low Back Disorders. *JOEM*. 2020:62(3);e111-e138. https://acoem.org/acoem/media/News-Library/Practice-Guidelines-Non_Invasive-Low-Back-Pain-March-2020-JOEM_1.pdf. . Accessed September 27, 2023.
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14. National Coverage Determination (NCD) for Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds (270.1), implementation date: 7/6/04 . https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=131&ncdver=3&keyword=Electrical%20Stimulation%20(ES)%20and%20Electromagnetic%20Therapy%20for%20the%20Treatment&keywordType=starts&areaId=s27&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1. Accessed: September 27,January 2023.
15. National Coverage Determination (NCD) for Treatment of Motor Function Disorders with Electric Nerve Stimulation (160.2), implementation date: 4/1/03. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=22&ncdver=2&keyword=Treatment%20of%20Motor%20Function%20Disorders%20with%20Electric%20Nerve%20Stimulation&keywordType=starts&areaId=s27&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1. Accessed September 27,January 2023.
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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 27, 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/17	2/21/17	2/21/17	Joint policy established
5/1/18	2/20/18	2/20/18	Routine policy maintenance, no change in policy status.
5/1/19	2/19/19		Routine policy maintenance, no change in policy status.
5/1/20	2/18/20		Routine policy maintenance, no change in policy status.
5/1/21	2/16/21		Routine policy maintenance, no change in policy status.
5/1/22	2/15/22		Routine policy maintenance, no change in policy status.
5/1/23	2/21/23		Routine policy maintenance, no change in policy status. (ds)
3/1/24	12/19/23		• Routine maintenance (slp) • Vendor managed: Northwood • Codes added as EI: A4556, A4557, 97014, 97032

Next Review Date: 4th Qtr. 2024

Pre-Consolidation Medical Policy History

BCN Policy Date	Comments
5/21/08	BCN policy established
11/2/09	Routine maintenance of experimental/investigational service
2/15/12	Routine review; no change in policy status; references updated. Also updated the rationale.
3/20/13	Routine maintenance. Policy status unchanged.
3/19/14	Routine maintenance. No additional references/studies found. No change in policy status.
3/18/15	Routine maintenance.
3/16/16	Routine maintenance, no change in policy status.

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: H-WAVE STIMULATION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to Government Regulations
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member’s certificate and is not guaranteed. Please consult the individual member’s certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.