The use of H-wave stimulation is considered **investigational** for all indications, including but not limited to:

- treatment of pain
- wound healing
- post-operative treatment to improve function and/or range of motion

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

**Cross-reference:**
- MP-6.020 Transcutaneous Electrical Nerve Stimulation
- MP-6.045 Sympathetic Therapy for the Treatment of Pain
- MP-6.046 Threshold Electrical Stimulation as a Treatment of Motor Disorders
- MP-6.047 Interferential Stimulation for Treatment of Pain
- MP-6.048 Electrical Stimulation for the Treatment of Arthritis and Miscellaneous Conditions
- MP-6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy

**II. PRODUCT VARIATIONS**

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

- BlueJourney HMO*
- BlueJourney PPO*
- FEP PPO**
**Refer to Centers for Medicare and Medicaid (CMS) National Coverage Determination (NCD) 160.12 Neuromuscular Electrical Stimulation (NMES).**

**The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.**

### III. Description/Background

H-wave stimulation is a distinct form of electrical stimulation, and an H-WAVE® device is U.S. Food and Drug Administration (FDA) -approved for medical purposes that involve repeated muscle contractions. H-wave electrical stimulation has been evaluated primarily as a pain treatment, but it has also been studied for other indications such as wound healing and improving post-surgical range of motion. 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. H-wave stimulation has been used for the treatment of pain related to a variety of etiologies, such as diabetic neuropathy, muscle sprains, temporomandibular joint dysfunctions, or reflex sympathetic dystrophy. 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.

H-wave electrical stimulation must be distinguished from the H-waves that are a component of electromyography.

**Regulatory Status**

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. 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.”

Uses of the device not cleared by the FDA include, but are not limited to, treatment of diabetic neuropathy and wound healing.

IV. RATIONALE

**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. (2) 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 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.

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. Blum and several co-investigators are consultants to the device manufacturer. Descriptions of the individual published studies are included below.

In 1997, Kumar and Marshall published an RCT comparing active H-wave electrical stimulation with sham stimulation for treatment of diabetic peripheral neuropathy. (3) 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 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. (4) 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 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 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 patients 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 (5) described a case series of 34 patients 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 and colleagues and consisted of patients’ responses to 3 of 10 questions on a manufacturer’s customer service questionnaire (i.e., warranty registration card). (6, 7) In the larger of the two reports, 80% of 8,498 patients with chronic soft tissue injury and neuropathic pain who were given the H-WAVE® device completed the questionnaire. (7) 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

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. (8)

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. (9) 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 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

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 other 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. Thus, H-wave electrical stimulation is considered investigational.

2015 Update

Review of the literature revealed no new information that would alter the conclusions reached above. Therefore, the policy statement is unchanged

2016 Update

Review of the literature revealed no new information that would alter the conclusions reached above. Therefore, the policy statement is unchanged

V. DEFINITIONS

510 (K) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.
VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered:

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<th>CPT Codes®</th>
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<table>
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<tr>
<th>HCPCS Code</th>
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<tr>
<td>E0745</td>
<td>Neuromuscular stimulator, electronic shock unit</td>
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IX. REFERENCES


Other Sources:
X. **Policy History**

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<td>CAC 10/30/2012</td>
<td>Consensus. No change to policy statement. References Updated. Codes reviewed 10/18/12</td>
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<tr>
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<td>CAC 11/25/2014</td>
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<td>Consensus review. No change to policy statements. References updated. Rationale reviewed. Changed FEP variation to refer to standard investigational statement - FEP policy was archived. Coding reviewed.</td>
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