Medical Policy Reference Manual
Medical Policy

1.01.005 ARCHIVED H-Wave Electrical Stimulation Devices for Home Use

Original MPC Approval: 03/22/1999
Last Review Date: 01/01/2023
Last Revision Date: 01/01/2023

Description

H-wave stimulation is a form of electrical stimulation which differs from other forms of electrical stimulation in terms of the characteristics of the electrical current applied. These devices are available for home use. H-wave electrical stimulation has been used in the treatment of acute or chronic pain, diabetic neuropathy, TMJ dysfunction, and reflex sympathetic dystrophy. It has also been used to accelerate wound healing, as in diabetic ulcers.

Policy

H-wave electrical stimulation devices for home use are considered **experimental / investigational**, as they do not meet TEC criteria # 2-5.

Policy Guidelines

Experimental/Investigational

The term "experimental/investigational" describes services or supplies that are in the developmental stage and are in the process of human or animal testing. Services or supplies that do not meet all 5 of the criteria listed below adopted by the BlueCross BlueShield Association Technology Evaluation Center (TEC) are deemed to be experimental/investigational:

1. The technology* must have final approval from the appropriate U.S. government regulatory bodies; and
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes; and
3. The technology must improve the net health outcome; and
4. The technology must be as beneficial as any established alternatives; and
5. The improvement must be attainable outside the investigational settings.

* Technology includes drugs, devices, processes, systems, or techniques

Rationale:

1. The technology must have final approval from the appropriate U.S. government regulatory bodies:

In 1992, the H-Wave® muscle stimulator (Electronic Waveform Lab, Huntington Beach, CA) device received 510(k) approval from the U.S. Food and Drug Administration (FDA) as a muscle stimulator. Uses not approved by the FDA include, but are not limited to, treatment of arthritis, migraine headaches, or diabetic neuropathy and wound healing.

2. The scientific evidence must permit conclusions concerning the effect on health outcomes:

There is a scarcity of peer-reviewed literature to support the effectiveness of H-wave electrical device stimulation (HWDS) when used in the home environment. Data is insufficient to allow conclusions as to whether H-wave electrical stimulation device enhances pain relief, wound healing, and postoperative rehabilitation. Williamson (2021) published a review of pre-clinical and clinical studies evaluating the H-Wave® device in the treatment of acute, chronic, or post-surgical musculoskeletal pain or loss of function. Sixteen studies (N=6789) were included in the review, however only nine of the studies reported clinical data. The trials, small cohort studies and case reports summarized study outcomes of reduced pain, improved function, and lower medication use with the device. The certainty of evidence assessed for all studies was low to moderate with study weaknesses including moderate risk of bias and lack of objective clinical

findings and no pooled analyses were conducted. In 2008 a systematic review with meta-analysis, of 5 studies evaluating the H-Wave device for treatment of chronic soft tissue inflammation and neuropathic pain was published. 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. And conclusions based on this meta-analysis lacked sufficient data from randomized, placebo-controlled studies and results were mainly based from case series. The research fails to show significant differences in outcomes amongst groups and concluded that evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit versus harm; additional research is recommended. (Blum. K. et al., 2008). Blum et al., (2009) looked at a randomized double-blind placebo controlled prospective study that assessed the effects of HWDS on range of motion and strength testing in patients who underwent rotator cuff reconstruction. Results concluded that there were no statistically significant differences between groups in postoperative strength and although HWDS compared to placebo induces a significant increase in range of motion in positive management of rotator cuff reconstruction, interpretation of this preliminary investigation warrants further confirmation in a larger double-blinded sham controlled randomized study.

3. The technology must improve the net health outcome:

Available research continues to reveal low quality, small sample size and fails to demonstrate H-wave electrical stimulation devices used at home improves pain or function for people with any condition. 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. Based on the lack of data, evidence fails to show that there is improvement in the net health outcome. No clinical guidelines based on research recommend H-wave stimulation, therefore the devices are considered investigational for all indications.

4. The technology must be as beneficial as any established alternatives:

There is inadequate research being performed comparing H-wave electrical stimulation devices for home use against other conservative treatments like splinting, rest, non-steroidal anti-inflammatory medications, physical therapy or, steroid injections. Due to the absence of data found for this indication there is no conclusive evidence that HWDS is better than any established alternatives and more long term follow up is needed.

5. The improvement must be attainable outside the investigational settings:

A net health outcomes improvement has not been demonstrated in the investigational settings. Therefore, it is not possible to determine whether an improvement outside of the investigational setting can be expected.

Update 2022:
A review of the current peer-reviewed literature was performed from the period of January 2019 through June 2022. No new literature was found supporting the use of H-wave electrical stimulation devices for home use. Therefore, the policy remains unchanged.

Update 2019:
A review of the current peer-reviewed literature was performed for the period of February 2017 through January 2019. No new literature was found relating to the use of H-wave electrical stimulation devices for home use. Therefore, the policy remains unchanged.

Update 2017:
A review of the current peer-reviewed literature was performed for the period of December 2014 through January 2017. No new literature was found relating to the use of H-wave electrical stimulation devices for home use. Therefore, the policy remains unchanged.

Update 2015:
A review of the current peer-reviewed literature was performed for the period of December 2012 through November 2014. Findings in the recent literature do not change the conclusions on the use of H-wave electrical stimulation devices for home use. Therefore, the policy remains experimental / investigational.

Update 2012:
A review of the current peer-reviewed literature was performed for the period of October 2010 through November 2012. Findings in the recent literature do not change the conclusions on the use of the H-Wave electrical stimulation devices for home use. Therefore, the policy remains experimental / investigational.

Update 2010:
A review of the current peer-reviewed literature was performed for the period of August 2008 through September 2010. No ongoing clinical trials were identified. Findings in the recent literature do not change the conclusions on the use of H-Wave electrical stimulation devices for home use. Therefore, the policy statement remains unchanged.

Update 2008:
A review of the current peer-reviewed literature was performed from July 2006 through July 2008. No published clinical trials were identified that would support the effectiveness of H-wave electrical stimulation devices when used in the home environment. Therefore, the policy statement remains unchanged.

Benefit Applications
NOTE: For FEP, check the member's contract for benefits.

Provider Guidelines
There are no Provider Guidelines for this Medical Policy.

Cross References to Related Policies and Procedures
1.01.018 Neuromuscular Electrical Stimulation (NMES) Devices, Policy

References
The following were among the resources reviewed and considered in developing this policy. By reviewing and considering the resources, CareFirst does not in any way endorse the contents thereof nor assume any liability or responsibility in connection therewith. The opinions and conclusions of the authors of these resources are their own and may or may not be in agreement with those of CareFirst.

August 2003 - A review of the MEDLINE database using the search strategy focused on references containing the following word: -H-wave Electrical Stimulation Device, failed to identify any clinical trials published in the peer reviewed literature

A review of the MEDLINE database using the search strategy focused on references containing the following word: -*H-wave*, failed to identify any clinical trials published in the peer reviewed literature.

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U.S. Food and Drug Administration (FDA). Premarket approval (PMA) database. Accessed May 26, 2022. Available at URL address: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

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