Medical Policy: H-Wave			
Physician Reviewer:	Elena Antonelli, M.D.	**Reviewed Date:**	07/06/2017
Specialty:	Occupational Medicine	**Established Date:**	10/23/2014
Referral Number	847385		

POLICY

- H-wave is an electrical stimulation device similar to transcutaneous electrical nerve stimulation (TENS). However, it differs in its wave-form, which is believed to allow for deeper tissue penetration. It has been used to treat musculoskeletal pain, reduce edema, promote wound healing, and treat diabetic neuropathy.
- Not recommended. At this time, its use is considered experimental by multiple organizations, agencies, and guidelines due to lack of proven efficacy. This includes the Agency for Healthcare Research and Quality (AHRQ), insurance companies, Aetna and BCBS, the ODG, and ACOEM. AHRQ's National Guideline Clearinghouse specifically does not recommend H-Wave and gives it a rating of I (Insufficient evidence). Aetna and BCNS concluded that H-Wave is investigational for all indications. The ODG cites a study that showed decreases in chronic soft tissue injury and neuropathic pain. However, it was uncontrolled. Other citations include results ranging from no difference in the analgesic effect between TENS and H-Wave to a short-lived 5-minute analgesic effect to no demonstrable analgesic effect. Overall, the ODG finds current studies to be of low quality, leading it to not recommend H-Wave. ACOEM's conclusions match those of the ODG. Although ACOEM finds H-Wave to have little potential adverse effect, it notes that the device is more costly than other electrical stimulators and that there are no quality studies evaluating it for treatment of neuropathic pain, CRPS, or other chronic pain conditions.

SUPPORTING DOCUMENTATION

ACOEM Practice Guidelines: Chronic Pain.
https://new.mdguidelines.com/Resources/ACOEM-Practice-Guidelines/Disorders/Chronic-Pain. (effective May 15, 2017)
Chronic Pain
Neuropathic Pain
Diagnostic and Treatment Recommendations
Electrical Therapies
H-Wave Device Stimulation for Neuropathic Pain
No Recommendation.
There is no recommendation for or against H-Wave Device Stimulation for treatment of neuropathic pain.
Strength of Evidence - No Recommendation, Insufficient Evidence (I)
Level of Confidence - Low

ACOEM Practice Guidelines: Chronic Pain.
https://new.mdguidelines.com/Resources/ACOEM-Practice-Guidelines/Disorders/Chronic-Pain. (effective May 15, 2017)
Chronic Pain
Complex Regional Pain Syndrome
Diagnostic and Treatment Recommendations
Electrical Therapies
H-Wave Device Stimulation for CRPS
No Recommendation.

There is no recommendation for or against H-Wave Device Stimulation for treatment of CRPS.
Strength of Evidence - No Recommendation, Insufficient Evidence (I)
Level of Confidence - Low

ACOEM Practice Guidelines: Chronic Pain.
https://new.mdguidelines.com/Resources/ACOEM-Practice-Guidelines/Disorders/Chronic-Pain. (effective May 15, 2017)
Chronic Pain
Persistent Pain
Diagnostic and Treatment Recommendations
Electrical Therapies
H-Wave Device Stimulation for Chronic Persistent Pain
No Recommendation.
There is no recommendation for or against H-Wave Device Stimulation for treatment of chronic persistent pain.
Strength of Evidence - No Recommendation, Insufficient Evidence (I)
Level of Confidence - Low

ODG Pain (updated 06/13/17) - Online version
H-Wave device stimulation
Not recommended as an isolated intervention but a one-month home-based trial of H-Wave may be considered as a noninvasive conservative treatment option in accordance with the criteria below. Continued use may be recommended if the trial results in less reported pain combined with increased functional improvement or medication reduction.
Criteria for use of H-Wave:
A. Home H-Wave may be considered on a trial basis if other noninvasive, conservative treatments for chronic pain have not proven successful, including all the following (unless contraindicated):
(1) Medication
(2) Physical Therapy (i.e., exercise)
(3) TENS
B. The one-month initial trial will permit the physician and PT provider to evaluate any effects and benefits. If continued use is prescribed there should be evidence of less reported pain combined with increased functional improvement or medication reduction.
C. While medical providers may perform H-Wave device stimulation, H-Wave devices are also available for home use. Rental would be preferred over purchase during a home trial.
Several PubMed and Medline indexed studies, with identified risks of bias, provide evidence about the effectiveness of the device. An RCT demonstrated improved post-operative ROM with the use of H-Wave device following rotator cuff reconstruction. (Blum, 2009) Two RCTs show reduction in chronic pain associated with diabetic peripheral neuropathy. (Kumar 1997) (Kumar 1998) A meta-analysis of predominantly uncontrolled studies indicated a moderate to strong effect of the H-Wave device in providing pain relief, reducing the requirement of pain medication and increasing functionality. The most robust effect was observed for improved functionality. (Blum, 2008) Uncontrolled studies of use of the H-Wave device in large numbers of patients with chronic soft tissue injury or neuropathic pain have reported reductions in pain and use of pain medication and improved functional capacity or activity. (Blum, 2006) (Blum2, 2006)
Note: According to the U.S. manufacturer of H-Wave, studies by McDowell were performed outside of the U.S. on an unrelated device sold by a company known as MIE, and the MIE device, although referred to using the designation "Hwave", is not cleared by the FDA, not sold in the U.S. and is not related to the H-Wave device sold in the U.S. As such, the McDowell studies were excluded.
How it works: The H-Wave device uses output parameters and a waveform that are distinct from other electrical stimulation devices, such as transcutaneous electrical nerve stimulation (TENS). One mode of operation is intended to shut down pain by affecting the function of the sodium pump, while a second mode of operation is intended to improve recovery through increased blood flow and perfusion. Studies on the mechanisms of action of the H-Wave device demonstrated that the H-Wave device induces arteriolar vasodilation via nitric oxide mediated mechanisms, increased blood flow and angiogenesis in test animals. (Smith 2009) (Smith 2011)

REFERENCE(S)

ACOEM Practice Guidelines: Chronic Pain.

https://new.mdguidelines.com/Resources/ACOEM-Practice-Guidelines/Disorders/Chronic-Pain. (effective May 15, 2017)

ODG Pain (updated 06/13/17) - Online version