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Medical Policy Manual

Topic: H-wave Stimulation

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

The proposed mechanism of H-wave stimulation is a bipolar, exponential decaying waveform that combines low and high frequency wave lengths, which are projected to provide muscle stimulation and analgesic pain control. H-wave electrical stimulation must be distinguished from the H-waves that are a component of electromyography.

Regulatory Status

The H-Wave® device is an example of this type electrical stimulation device, which has received 510(k) approval from the U.S. Food and Drug Administration (FDA) as a muscle stimulator. Approved uses for this device include: treatment of muscle spasm, deterrence or reduction of muscle disuse atrophy, and improvement of muscle range of motion, among others. Uses not approved by the FDA include, but are not limited to, treatment of arthritis, migraine headaches, or diabetic neuropathy and wound healing.[1]

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.

MEDICAL POLICY CRITERIA

H-wave stimulation devices are considered **investigational** for all indications, including but not limited the treatment of pain.

SCIENTIFIC EVIDENCE

The principal outcomes associated with treatment of pain due to any cause may include: relief of pain, improved functional level, and return to work. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore, data from adequately powered, blinded, randomized controlled trials (RCTs) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from an electrical stimulation device provides a significant advantage over the placebo.

Treatment with an electrical stimulation device must also be evaluated in general groups of patients against the existing standard of care for the condition being treated. For example, in patients with pain symptoms, treatment with an electrical stimulation device should be compared with other forms of conservative therapy such as splinting, rest, non-steroidal anti-inflammatory medications, physical therapy, or steroid injection.

Literature Appraisal

Several large case series and a handful of small RCTs have been conducted on the use of H-Wave stimulation for the treatment of pain. A meta-analysis, combining results from randomized and non-randomized trials, has also been published.

Meta-Analysis

A meta-analysis, supported in part by a device manufacturer (Electronic Waveform Lab, Inc.) was published in 2008 and reported on 5 studies using the H-Wave device for the treatment of pain.[2] However, conclusions based on this meta-analysis are limited by the lack of sufficient data from randomized, placebo-controlled studies and are based mainly upon results from case series.

Randomized Controlled Trials

Two small RCTs (n=31 and 23) evaluated the efficacy of H-wave electrical stimulation in the treatment of diabetic peripheral neuropathy, and one small study evaluated the effects of H-wave stimulation on range of motion and strength testing in patients who underwent rotator cuff reconstruction.[3-5] However, the studies were unreliable due to at least one of the following reasons:

- The small study population (≤100) limited the ability to rule out the role of chance as an explanation of findings.
- The attrition of study subjects and blinding was either not reported or not adequately addressed in the analysis, potentially undermining comparability of treatment groups.

Clinical Practice Guidelines

There are no evidence-based clinical practice guidelines that recommend the use of H-wave electrical stimulation devices for the treatment of pain or any other indication.

In two evidence-based clinical practice guidelines which included only high- and moderate-quality randomized controlled clinical trials or cross-over trials, the American College of Occupational and Environmental Medicine specifically recommended against H-wave stimulation for treatment of acute and chronic pain, including all of the following:[6,7]

- 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

Summary

Based on the lack of published long-term objective outcomes from well-designed, well-executed randomized controlled clinical trials, conclusions cannot be reached concerning the effectiveness of H-wave stimulation as a treatment of pain or any other condition. In addition, the FDA has specifically excluded several proposed indications for this device, and evidence-based clinical practice guidelines recommend against the use of H-wave stimulation for the treatment of acute and chronic pain. Therefore, H-wave stimulation is considered investigational for all indications.

Larger, randomized, placebo- controlled trials of longer duration are needed to evaluate the effectiveness of H-wave stimulation devices in improving pain and function and to determine whether H-wave stimulation offers any additional benefit compared with sham treatment or other standard treatments.

REFERENCES

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CROSS REFERENCES

Electrical Stimulation Devices Index, Durable Medical Equipment, Policy No. 83

CODES	NUMBER	DESCRIPTION
CPT	None	
HCPCS	E1399	Durable medical equipment, miscellaneous