MEDICAL POLICY

POLICY TITLE	H-WAVE ELECTRICAL STIMULATION
POLICY NUMBER	MP-6.049

Original Issue Date (Created):	**3/1/2012**
Most Recent Review Date (Revised):	**9/6/2018**
Effective Date:	**11/1/2018**

I. POLICY

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 Current Stimulation
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 (PNT)

II. PRODUCT VARIATIONS

TOP

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

FEP PPO: 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.

POLICY TITLE	H-WAVE ELECTRICAL STIMULATION
POLICY NUMBER	MP-6.049

III. DESCRIPTION/BACKGROUND

TOP

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. 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.

IV. RATIONALE

TOP

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.

2018 Update
Review of the literature revealed no new information that would alter the conclusions reached above. Therefore, the policy statement is unchanged.

V. DEFINITIONS

TOP

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.

POLICY TITLE	H-WAVE ELECTRICAL STIMULATION
POLICY NUMBER	MP-6.049

VI. BENEFIT VARIATIONS

TOP

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 BlueCross for benefit information.

VII. DISCLAIMER

TOP

Capital BlueCross 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 BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

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:

CPT Codes®								
97014								

HCPCS Codes	Description
E0745	Neuromuscular stimulator, electronic shock unit
G0283	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care

IX. REFERENCES

TOP

1. *Blum K, Chen AL, Chen TJ et al. The H-Wave device is an effective and safe non-pharmacological analgesic for chronic pain: a meta-analysis. Adv Ther 2008; 25(7):644-57.*
2. *Kumar D, Marshall HJ. Diabetic peripheral neuropathy: amelioration of pain with transcutaneous electrostimulation. Diabetes Care 1997; 20(11):1702-5.*
3. *Kumar D, Alvaro MS, Julka IS et al. Diabetic peripheral neuropathy. Effectiveness of electrotherapy and amitriptyline for symptomatic relief. Diabetes Care 1998; 21(8):1322-5.*
4. *Julka IS, Alvaro M, Kumar D. Beneficial effects of electrical stimulation on neuropathic symptoms in diabetes patients. J Foot Ankle Surg 1998; 37(3):191-4.*
5. *Blum K, DiNubile NA, Tekten T et al. H-Wave, a nonpharmacologic alternative for the treatment of patients with chronic soft tissue inflammation and neuropathic pain: a preliminary statistical outcome study. Adv Ther 2006; 23(3):446-55.*
6. *Blum K, Chen TJ, Martinez-Pons M et al. The H-Wave small muscle fiber stimulator, a nonpharmacologic alternative for the treatment of chronic soft-tissue injury and neuropathic pain: an extended population observational study. Adv Ther 2006; 23(5):739-49.*
7. *Blum K, Chen AL, Chen TJ et al. Healing enhancement of chronic venous stasis ulcers utilizing H-WAVE® device therapy: a case series. Cases J 2010; 3:54.*
8. *Blum K, Chen AL, Chen TJ et al. Repetitive H-wave device stimulation and program induces significant increases in the range of motion of post-operative rotator cuff reconstruction in a double-blinded randomized placebo controlled human study. BMC Musculoskelet Disord 2009; 10:132.*

X. POLICY HISTORY

TOP

MP 6.049	**CAC 10/25/2011 -** Adopted BCBSA. Removed information regarding H-wave electrical stimulation from MP-6.020, Electrical Stimulation Modalities and created separate policy. Remains investigational for all indications.
	CAC 10/30/12 Consensus. No change to policy statement. References Updated. Codes reviewed 10/18/12
	CAC 11/26/13 Consensus, no change to policy statements. References updated. Rationale section added. Added Medicare variation to reference NCD 160.12. FEP variation changed to standard statement.

POLICY TITLE	H-WAVE ELECTRICAL STIMULATION
POLICY NUMBER	MP-6.049

	CAC 11/25/14 Consensus review. No changes to the policy statements. References updated. FEP variation revised to refer to the FEP policy manual.
	CAC 11/24/15 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.
	CAC 9/27/16 Consensus. No change to policy statements. References updated. Rationale reviewed. Variation reformatted. Coding reviewed.
	CAC 11/28/17 Consensus review. No change to the policy statements. References reviewed. Coding reviewed and updated.
	9/06/18 Consensus review. Policy statements unchanged. Description/Background and Rationale sections updated. References reviewed.

Top