MEDICAL POLICY

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

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**2/1/2024**

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 general 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

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO: Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

Note* - The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

III. DESCRIPTION/BACKGROUND

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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

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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.

Review of recent literature suggests that there may perhaps be some benefits of H-Wave Electrical Stimulation, providing clinically significant improvements in pain. This may be particularly important in a landscape of opioid crisis, as Williamson et. Al noted that “H-Wave electrical stimulation may be an adjunctive component of non-opioid multi-modal pain management.” However, the recent literature also ultimately concludes that at this time, higher quality research is needed (Williamson, et al), and more rigorous long-term clinical trials are needed to further validate appropriate use and specific indications for most forms of electrical stimulation (Allen, et. Al).

V. DEFINITIONS

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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

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross'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. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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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:

Procedure Codes								
E0745	G0283	97014						

IX. REFERENCES

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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. PMID*
2. *Kumar D, Marshall HJ. Diabetic peripheral neuropathy: amelioration of pain with transcutaneous electrostimulation. Diabetes Care 1997; 20(11):1702-5. PMID*
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. PMID*
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. PMID*

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. PMID

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. PMID

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. PMID

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. PMID

9. Williamson TK, Rodriguez HC, Gonzaba A, Poddar N, Norwood SM, Gupta A. H-Wave® Device Stimulation: A Critical Review. J Pers Med. 2021;11(11):1134. Published 2021 Nov 2. doi:10.3390/jpm1111113

10. Bajaj A, Han D, Elman I, et al. Positive Clinical Outcomes for Severe Reported Pain Using Robust Non-Addictive Home Electrotherapy-A Case-Series. J Pers Med. 2023;13(2):336. Published 2023 Feb 15. doi:10.3390/jpm13020336

11. Allen CB, Williamson TK, Norwood SM, Gupta A. Do Electrical Stimulation Devices Reduce Pain and Improve Function?-A Comparative Review. Pain Ther. 2023;12(6):1339-1354. doi:10.1007/s40122-023-00554-6

12. Blue Cross Blue Shield Association Medical Policy Reference Manual. 1.01.13, H-Wave Electrical Stimulation. November, 2012 (Archived).

X. POLICY HISTORY

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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 review. No change to policy statement. References Updated. Codes reviewed 10/18/12
	CAC 11/26/13 Consensus review. No change to policy statements. References updated. Rationale section added. Added Medicare variation to reference NCD 160.12. FEP variation changed to standard statement.
	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 review. 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.
	5/29/2019 Consensus review. No change to the policy statements.
	References reviewed.
	4/14/2020 Consensus Review. No change to policy statement. References reviewed. Coding sheet checked with no new codes. Claims report completed.
	8/3/2021 Consensus Review. No change to policy statement. References and coding reviewed.
	9/16/2022 Consensus Review. No change to policy statement. FEP, references updated. Coding reviewed, no changes.
	11/3/2023 Consensus Review. No changes to policy statement. Rationale, references updated. Coding reviewed, no changes.

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