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Medical Policy Manual Durable Medical Equipment, Policy No. 83.03

Microcurrent Stimulation (MENS)

Effective: February 1, 2019

Next Review: November 2019
Last Review: January 2019

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

A microcurrent electrical neuromuscular or nerve stimulation (MENS) device is characterized by tiny, sub-sensory currents that are described as being similar to the body's naturally occurring electrical impulses. MENS devices are proposed to decrease pain and facilitate the healing process.

MEDICAL POLICY CRITERIA

Microcurrent stimulation devices are considered **investigational** for all indications, including but not limited to the treatment of anxiety, cognitive dysfunction, depression, fibromyalgia, insomnia, migraine headache, and other pain disorders.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

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

BACKGROUND

REGULATORY STATUS

An example of a microcurrent electrical stimulation device used for pain management is the Alpha-Stim PPM® (personal pain manager). Additional AlphaStim devices for cranial electrostimulation therapy (CES) are addressed in Medical Policy, DME, Policy No. 83.06, Cranial Electrostimulation Therapy.

More than 100 electrical stimulation devices have received 510(k) approval from the U.S. Food and Drug Administration (FDA). Marketing clearance via the 510(k) process does not require data regarding clinical efficacy.

EVIDENCE SUMMARY

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 a placebo device.

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, or physical therapy.

MENS has been studied mainly for the use of pain and sore muscle relief in several small, RCTs.

SYSTEMATIC REVIEWS

No systematic reviews (SRs) were identified.

RANDOMIZED CONTROLLED TRIALS

Kwon (2017) published a RCT that evaluated the impact of MENS for age related muscle weakness.[1] Thirty-eight participants age 65 and above were given MENS (n=19) or sham treatment (n=19) for 40 minutes. The authors concluded MENS can improve muscle function in the elderly, but the study had methodological limitations, including lack of long-term follow-up and the inability to determine how applicable the results were for all elderly patients.

Several small RCTs investigated MENS for a variety of indications, including, pain associated with mandibular dysfunction,[2] epidural fentanyl requirements and degree of wound healing after total hip arthroplasty,[3] masticatory muscle pain,[4] pain from diabetic neuropathy,[5] and primary burn wounds.[6] However, the results from these studies are unreliable due to small study populations, which limit the ability to rule out the role of chance as an explanation of findings,[2-6] and short follow-up periods.[4-6]

Several small, RCTs (n< 40) examined the effect of MENS on exercise-induced muscle

soreness in healthy volunteers.[7-9] However, the responses in healthy volunteers may differ from those of patients with clinical diagnoses requiring treatment and rehabilitation.

PRACTICE GUIDELINE SUMMARY

There are no evidence-based clinical practice guidelines that recommend the use of MENS devices.

SUMMARY

There is not enough research to show that microcurrent stimulation improves health outcomes for people with any condition. No clinical guidelines based on research recommend the use of microcurrent electrical stimulation devices for any condition. Therefore, microcurrent devices are considered investigational for all indications.

REFERENCES

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CODES

Codes	Number	Description
CPT	None	
HCPCS	E1399	Durable medical equipment, miscellaneous

Date of Origin: *January 2012*