

Medical Policy Manual

Topic: Microcurrent Stimulation (MENS)

Date of Origin: January 2012

Section: DME

Last Reviewed Date: December 2013

Policy No: 83.03

Effective Date: February 1, 2014

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 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.

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.

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.

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 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.

Literature Appraisal

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

Randomized Controlled Trials

The MENS RCTs are limited in quantity and quality. Several small RCTs investigated MENS for a variety of indications:

- Pain associated with mandibular dysfunction^[1]
- Epidural fentanyl requirements and degree of wound healing after total hip arthroplasty^[2]
- Masticatory muscle pain^[3]
- Pain from diabetic neuropathy^[4]

However, the results from these studies are unreliable due to at least one of the following methodological limitations:

- The small study population (≤ 100) limited the ability to rule out the role of chance as an explanation of findings.^[1-4]
- The short follow-up periods limited conclusions regarding the durability of treatment effects.^[3,4]

Several small, randomized trials ($n < 40$) examined the effect of MENS on exercise-induced muscle soreness in healthy volunteers.^[5-7] However, the responses in healthy volunteers may differ from those of patients with clinical diagnoses requiring treatment and rehabilitation.

Clinical Practice Guidelines

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

In evidence-based clinical practice guidelines, which included only high- and moderate-quality randomized controlled clinical trials or crossover trials, the American College of Occupational and Environmental Medicine (ACOEM) specifically recommended against microcurrent stimulation for treatment of acute and chronic pain, including all of the following:^[8-10]

- Complex regional pain syndrome
- Neuropathic pain (focus on radicular pain and peripheral neuropathic pain)
- Trigger Points/Myofascial Pain
- Chronic persistent pain
- Acute, subacute and chronic low back pain
- Acute, subacute and chronic cervicothoracic pain

The ACOEM made no recommendation for or against the use of MENS for the following indications, based on an I* rating:^[11,12]

- Shoulder dislocation and instability
- Superior labral anterior posterior (SLAP) and other labral tears
- Acromioclavicular sprains or dislocations
- Shoulder (glenohumeral and acromioclavicular joint) osteoarthritis
- Adhesive capsulitis ("frozen shoulder" and "painful stiff shoulder")
- Total knee arthroplasty postoperative pain control

*I = "The evidence is insufficient to recommend for or against routinely providing the intervention. The EBPP makes no recommendation. Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined."^[11,12]

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 microcurrent stimulation as a treatment of pain or any other condition; therefore, MENS is considered investigational for all indications. Larger, randomized, placebo- controlled trials of longer duration are needed to evaluate the effectiveness of MENS devices in improving pain and function and to determine whether MENS offers any additional benefit compared with sham treatment or other standard treatments.

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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