Regence

Medical Policy Manual Durable Medical Equipment, Policy No. 83.03

Microcurrent Stimulation (MENS)

Effective: March 1, 2025

Next Review: November 2025
Last Review: January 2025

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. Threshold Electrical Stimulation as a Treatment of Motor Disorders, Durable Medical Equipment, Policy No. 83.05
2. Cranial Electrostimulation Therapy (CES), Durable Medical Equipment, Policy No. 83.06
3. Interferential Current Stimulation, Durable Medical Equipment, Policy No. 83.07
4. Electrical Stimulation for the Treatment of Wounds, Durable Medical Equipment, Policy No. 83.09
5. Electrical Stimulation for the Treatment of Arthritis, Durable Medical Equipment, Policy No. 83.10

6. Electromagnetic Therapy, Durable Medical Equipment, Policy No. 83.13

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.

Microcurrent electrical neuromuscular or nerve stimulation (MENS) has been studied mainly for the use of pain and sore muscle relief in several small RCTs.

SYSTEMATIC REVIEWS

Bavarian (2021) published a systematic review and meta-analysis to assess the efficacy of MENS therapy in treating myofascial pain of the masticatory muscles.[1] Four independent comparisons based on three studies were included in the meta-analysis (n=140). In comparison to placebo and other therapies, treatment with MENS showed an improved mean reduction in pain of -0.57 points (confidence interval[CI] -0.91 to -0.23 points, I^2=83.7%). The authors comment that “the study was limited by the small number of articles relevant to the research question as well as variability between the selected studies”.

Lijima (2021) published a systematic review of data from four RCTs investigating the effects of MENS on musculoskeletal pain in adults.[2] Data from nonrandomized studies also were included to assess adverse events. Clinical populations studied included patients with chronic neck pain, chronic low back pain (LBP), knee pain, tennis elbow, and subacromial impingement-induced shoulder pain. In total, nine studies were included in the review, four (40.0%) of which were RCTs in which MENS was used to treat adults with subacromial impingement-induced shoulder pain (one RCT), chronic LBP (one RCT), or knee pain (two RCTs). Meta-analysis found MENS did not improve chronic LBP but did significantly improve subacromial impingement-induced shoulder pain and subacute to chronic knee pain compared

with sham MENS. The authors also found that *sham* MENS significantly improved subacute to chronic knee pain to an extent that was considered clinically meaningful. The quality of evidence for shoulder pain and LBP was “moderate” and “low”, respectively, attributed to risk of bias or small sample size. For subacute to chronic knee pain, the level of evidence was “high”. Only one RCT in 52 subjects compared MENS to sham in the treatment of knee pain and the follow-up in this study was limited to four weeks. Studies comparing MENS with other treatment approaches to musculoskeletal pain were not included in the review.

A systematic review of evidence evaluating the effect of continuous electrical microcurrent on wound healing was published by Ofstead (2020). Of the 13 studies included, only four evaluated electrode-based units. Three of these trials evaluated the Accel-Heal system and one compared transcutaneous electrical nerve stimulation (TENS) and traditional silver dressings. Review of all studies found small sizes and considerable heterogeneity in the control or standard of care to which treatment was compared. Despite these limitations, the authors note the treatment is considered safe and effective with “generally better outcomes” than standard of care. This review was supported by an unrestricted grant by a device manufacturer (Vomaris Innovations, Inc) and study authors received funding related to wound healing from the company, however the authors note the company did not have a role in study design, collection, analysis, or writing.

RANDOMIZED CONTROLLED TRIALS

Avendaño-Coy (2022) published a randomized trial to assess the effectiveness of microcurrent therapy for healing pressure ulcers in aged people.[3] A multicentric, RCT was designed with a sham stimulation control. The experimental group received an intervention following a standardized protocol for curing ulcers combined with 10 hours of microcurrent therapy daily for 25 days. The sham group received the same curing protocol plus a sham microcurrent stimulation. The studied healing-related variables were the Pressure Ulcer Scale for Healing (PUSH) and the surface, depth, grade, and number of ulcers that healed completely. Three evaluations were conducted: pre-intervention (T1), 14 days following the start of the intervention (T2), and one day after the intervention was completed (T3). In total, 30 participants met the inclusion criteria (n=15 in each group). The improvement in the PUSH at T2 and T3 was 16.8% (95% CI 0.5 to 33.1) and 25.3% (95% CI 7.6 to 43.0) greater in the experimental group versus the sham control, respectively. The reduction in the wound area at T2 and T3 was 20.1% (95% CI 5.2 to 35.0) and 28.6% (95% CI 11.9 to 45.3) greater in the experimental group versus the control, respectively. Limitations to this trial includes the small sample size.

An RCT published by Miguel (2020) assessed the used of MENS in palatal wound healing. In this trial 53 patients were randomly assigned to a treatment group (n=26) or sham group (n=27) and received MENS or sham application of electrotherapy following free gingival graft (FGG) harvest. Clinical and patient-centered outcomes, as well as inflammatory markers were evaluated up to 90 days postoperatively. Earlier wound closure ($p<0.001$) and epithelialization ($p<0.05$, $p=0.03$) was found at seven and 14 days after harvest in the treatment compared to the sham group. Painful symptomatology was reported less frequently in the treatment group than in the sham group at three-day follow-up ($p<0.01$). The small size of this trial limits the ability to rule out the role of chance as an explanation of findings and generalizability to broader patient populations.

The results of an RCT of MENS for the treatment of acute knee pain was published by Lawson (2020). Participants in the treatment (n=26) and control groups (n=26) wore an active microcurrent therapy or sham device at home for three hours per day for four weeks. Self-reported pain and function scales were the primary endpoints and musculoskeletal ultrasound imaging was used to assess effusion as a secondary endpoint. A greater reduction in the reporting of worst pain from baseline to week three was found in the treatment group over the control group ($p<0.01$), but no significant difference between groups was found at weeks one, two, or four. No significant difference was found for any other outcome measures between groups. In this industry-sponsored (Omron Health) study, the authors note that the device manufacturer participated in the design of the study but did not participate in the analysis or interpretation of the results. Limitations to this trial include small sample size and short duration.

Kwon (2017) published a trial that evaluated the impact of MENS for age related muscle weakness.[4] 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,[5] epidural fentanyl requirements and degree of wound healing after total hip arthroplasty,[6] masticatory muscle pain,[7] sinus pain,[8] pain from diabetic neuropathy,[9] and primary burn wounds.[10 11] 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, and short follow-up periods.

Several small RCTs (n<40) examined the effect of MENS on exercise-induced muscle soreness in healthy volunteers.[12-14] However, the responses in healthy volunteers may differ from those of patients with clinical diagnoses requiring treatment and rehabilitation.

NONRANDOMIZED STUDIES

Kurz conducted a multi-center observational study examining the effects of microcurrent stimulation on pain and wounds that were not responding to standard care and other advanced therapies[15]. Wounds were monitored via clinical signs, pain, area, and depth assessments, and pain was assessed using a visual analog scale (VAS). Pain was assessed at day 0, 48 hours post, 7- and 14-days post-treatment and clinical responses were assessed at 14-days post-treatment. Overall, 39 patients were treated, seven of which were post-surgical, three trauma, twelve diabetic foot, ten venous, four pressure injuries, and four mixed venous or arterial arteries were treated. Overall, 78% of wounds showed a marked positive clinical response and 96% of patients experienced a wound pain reduction within 48 hours of receiving treatment. All patients who reported painful wounds experienced a 45% pain reduction within seven days, and further reduction (33%) within 14 days. Further research is needed to determine if microcurrent stimulation improves patient outcomes more than other methods of treatment.

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

1. Bavarian R, Khawaja SN, Ajisafe AH, et al. The efficacy of microcurrent electrical nerve stimulation in treating masticatory myofascial pain: A systematic review and meta-analysis. *Cranio.* 2021:1-7. PMID: 34957937
2. Iijima H,Takahashi M. Microcurrent Therapy as a Therapeutic Modality for Musculoskeletal Pain: A Systematic Review Accelerating the Translation From Clinical Trials to Patient Care. *Arch Rehabil Res Clin Transl.* 2021;3(3):100145. PMID: 34589695
3. Avendano-Coy J, Martin-Espinosa NM, Ladrinan-Maestro A, et al. Effectiveness of Microcurrent Therapy for Treating Pressure Ulcers in Older People: A Double-Blind, Controlled, Randomized Clinical Trial. *Int J Environ Res Public Health.* 2022;19(16). PMID: 36011679
4. Kwon DR, Kim J, Kim Y, et al. Short-term microcurrent electrical neuromuscular stimulation to improve muscle function in the elderly: A randomized, double-blinded, sham-controlled clinical trial. *Medicine.* 2017;96(26):e7407. PMID: 28658177
5. Bertolucci LE,Grey T. Clinical comparative study of microcurrent electrical stimulation to mid-laser and placebo treatment in degenerative joint disease of the temporomandibular joint. *Cranio.* 1995;13(2):116-20. PMID: 8697497
6. Sarhan TM,Doghem MA. Effect of microcurrent skin patch on the epidural fentanyl requirements for post operative pain relief of total hip arthroplasty. *Middle East J Anesthesiol.* 2009;20(3):411-5. PMID: 19950736
7. Rajpurohit B, Khatri SM, Metgud D, et al. Effectiveness of transcutaneous electrical nerve stimulation and microcurrent electrical nerve stimulation in bruxism associated with masticatory muscle pain--a comparative study. *Indian J Dent Res.* 2010;21(1):104-6. PMID: 20427917
8. Maul XA, Borchard NA, Hwang PH, et al. Microcurrent technology for rapid relief of sinus pain: a randomized, placebo-controlled, double-blinded clinical trial. *International forum of allergy & rhinology.* 2019;9(4):352-56. PMID: 30667597
9. Gossrau G, Wahner M, Kuschke M, et al. Microcurrent transcutaneous electric nerve stimulation in painful diabetic neuropathy: a randomized placebo-controlled study. *Pain Med.* 2011;12(6):953-60. PMID: 21627767
10. Malin EW, Galin CM, Lairet KF, et al. Silver-coated nylon dressing plus active DC microcurrent for healing of autogenous skin donor sites. *Annals of plastic surgery.* 2013;71(5):481-4. PMID: 23903090
11. Ibrahim ZM, Waked IS,Ibrahim O. Negative pressure wound therapy versus microcurrent electrical stimulation in wound healing in burns. *Journal of wound care.* 2019;28(4):214-19. PMID: 30975055

12. Lambert MI, Marcus P, Burgess T, et al. Electro-membrane microcurrent therapy reduces signs and symptoms of muscle damage. *Med Sci Sports Exerc.* 2002;34(4):602-7. PMID: 11932567
13. Weber MD, Servedio FJ,Woodall WR. The effects of three modalities on delayed onset muscle soreness. *J Orthop Sports Phys Ther.* 1994;20(5):236-42. PMID: 7827630
14. Allen JD, Mattacola CG,Perrin DH. Effect of microcurrent stimulation on delayed-onset muscle soreness: a double-blind comparison. *J Athl Train.* 1999;34(4):334-7. PMID: 16558582
15. Kurz P, Danner G, Lembelembe JP, et al. Activation of healing and reduction of pain by single-use automated microcurrent electrical stimulation therapy in patients with hard-to-heal wounds. *Int Wound J.* 2023;20(6):2053-61. PMID: 36601702

CODES

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

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