


MEDICAL POLICY	Microcurrent Electrical Nerve Stimulation (MENS)
Effective Date: 06/01/2021	Medical Policy Number: 114
 6/1/2021	Technology Assessment Committee Approved Date: 4/11; 5/13; 5/14; 5/15; 5/16 Medical Policy Committee Approved Date: 7/17; 6/18; 8/19; 03/2020; 05/2021
Medical Officer	Date

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

- I. Microcurrent electrical nerve stimulation (MENS), including frequency-specific microcurrent (FSM), is considered **investigational and not covered** as a treatment of any condition.

Link to [Policy Summary](#)

BILLING GUIDELINE

When billed through eviCore for physical therapy/occupational therapy services, 97032 requires prior authorization.

MEDICAL POLICY	Microcurrent Electrical Nerve Stimulation (MENS)
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CPT/HCPCS CODES

All Lines of Business	
Prior Authorization Required	
97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as not covered .	
E1399	Durable medical equipment, miscellaneous
A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPCS code
A9999	Miscellaneous DME supply or accessory, not otherwise specified

DESCRIPTION

Microcurrent electrical nerve stimulation (MENS), also referred to as microelectrical therapy (MET) or microelectrical neurostimulation, involves applying a very low-voltage microamperage current to affected cells or tissue trigger points in order to stimulate the tissues’ response to healing and repair.

MENS differs from TENs in that it uses a significantly reduced level of electrical stimulation. TENS therapy delivers stimulation in the milliamp range, causing muscle contractions, pulsing and tingling, thereby blocking pain. Conversely, MENS delivers stimulation in the micro amp range, which is undetectable to patients and is thought to act on the body’s naturally occurring electrical impulses to decrease pain by stimulating the healing process.

During MENS therapy, the physical therapist or physician administers the microamperage current to various parts of the patient’s body by using vinyl graphite gloves or electrodes. The amount of current, length of individual sessions, as well as frequency and length of overall treatment has not been optimized for any given condition, and therefore may vary significantly. MENS has been proposed as both an adjunctive and a stand-alone therapy for a wide variety of indications that require either pain reduction or stimulation of the healing process. Due to variability in published MENS treatment protocols and the fact that MENS is often used in combination with a variety of other interventions, evaluating the efficacy of MENS for any condition is difficult.

REVIEW OF EVIDENCE

The use of randomized controlled trials (RCTs) is critical in evaluating any intervention in which clinically relevant outcomes consist of subjective, self-reported improvements in pain, function and disability, since these outcomes may be influenced by nonspecific effects like placebo response and the natural history of the disease. As a result, when randomization is used, differences in reported outcomes between treatment groups may be attributed to the treatment in question. In addition, comparative,

randomized studies must be sufficiently powered in order to eliminate any spurious results due to chance, and to allow generalizability of results. Ideally, long-term, randomized studies are recommended to determine potential sustained benefits. Therefore, the evidence review below has focused on RCTs comparing MENS to other interventions.

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of microcurrent electrical nerve simulation (MENS) as a treatment for any condition. Below is a summary of the available RCTs and systematic reviews identified through February 2021.

Systematic Reviews

- In 2018 (updated 2021), Hayes assessed the safety and efficacy of microcurrent electrical therapy (MET) for the treatment of postoperative pain.¹ In total, 3 RCTs were identified which evaluated MET for the treatment of postoperative pain following total knee arthroplasty (TKA) (2 studies) and total hip arthroplasty (THA) (1 study). Comparators included fentanyl infusion only, tramadol only, sham MET w/ physiotherapy. Outcomes of interest included: pain (visual analogue scale; disability and function; pain medication use; and complications. Sample sizes ranged from 24 to 89 patients with follow-up ranging from none to 3 months. Studies were conducted in Egypt and Germany. Two studies reported reduced medication use; two studies noted improved pain, disability and function, and 2 studies found that MET did not improve pain. Investigators concluded that overall body of evidence was “very-low-quality” due to studies’ small sample sizes, a lack of reporting of baseline demographics and a lack of statistical analyses. Patient selection criteria for the use of MET have also not yet been established. Authors stated that the current body of evidence is insufficient to draw conclusions regarding the efficacy and safety of MET for postoperative pain reduction.
- In 2018 (updated 2021), Hayes assessed the safety and efficacy of microcurrent electrical therapy for the treatment of musculoskeletal pain.² In total, 6 studies were identified – 2 evaluating MET for the treatment of lateral epicondylitis and 4 studies (1 study per indication) evaluated MET for the treatment of pain associated with lower back pain, Achilles tendinopathy, temporomandibular joint (TMJ) disorders, and bruxism. Comparators included Sham MET, occlusal splint, TENS, UC and exercise, exercise alone. Outcomes of interest included: Pain and tenderness (6 studies); treatment success (1 study); quality of life (1 study); analgesic use (1 study); and complications (1 study). Sample sizes ranged from 10 to 60 patients with follow-up varying from none to 50 weeks following end of treatment. Studies were conducted in Brazil, China, Germany, India, the Netherlands, Russia, United Kingdom.

For lateral epicondylitis MET plus usual care (UC) or exercise: one study reported improvements in pain in compared with sham treatment plus UC. One study did report improved pain compared with exercise alone. For pain associated with LBP MET compared with sham treatment, 1 study found no improvement in pain, quality of life, or analgesic use. For pain associated with Achilles tendinopathy MET plus exercise compared with UC, 1 study reported Improved pain, stiffness, and disability. For pain associated with TMJ MET alone or MET plus an occlusal splint, 1 study reported no improvement in pain compared with an occlusal splint alone or sham treatment with an occlusal splint. For pain associated with bruxism MET compared with transcutaneous electrical nerve stimulation, pain and tenderness were improved in 1 study.

Investigators concluded that the “very low quality” body of evidence was insufficient to assess the efficacy of MET for the treatment of pain associated with lateral epicondylitis or other musculoskeletal pain indications. Authors noted substantial uncertainty remaining regarding whether MET provides reduction in pain compared with usual care in patients with lateral epicondylitis. There is insufficient evidence to assess the efficacy of MET for the treatment of pain associated with lower back disorders, Achilles tendinopathy, TMJ disorders, or bruxism. These conclusions were due to a lack of consistent, high-quality evidence evaluating MET in any one indication.

- In 2020, Ofstead and colleagues evaluated the effect of continuous electrical microcurrent on wound healing.³ Investigators systematically searched the literature through 2019, identified eligible studies, assessed study quality and extracted data. In total, 13 studies were included for review, only four of which evaluated electrode-based units. Three of these trials evaluated the Accel-Heal system and one compared trans-cutaneous electrical nerve stimulation (TENS) and traditional silver dressings. Studies reported that electroceutical devices (ECDs) were effective in healing complex, hard-to-heal wounds that had not responded to other treatments. Four studies showed that ECDs led to complete closure of wounds without complications, and in some cases healed wounds faster than standard of care (SOC). On the basis of these findings, authors concluded that MENS is safe and effective with “generally better outcomes” than standard of care. Validity was limited, however, by the included studies’ small sizes, heterogeneous comparator groups and heterogeneous treatment parameters. Additionally, authors reported financial conflicts of interest with a MENS device manufacturer.

Randomized Controlled Trials

Small RCTs have evaluated MENS as a potential therapy for a variety of indications, including:

- Achilles tendinopathy⁴
- acute knee pain⁵
- age related muscle deterioration and damage⁶
- bruxism-induced masticatory muscle pain⁷
- cerebral palsy⁸⁻¹⁰
- chronic nonspecific low back pain¹¹
- chronic rhinosinusitis¹²
- chronic tennis elbow¹³
- congenital muscular torticollis^{14,15}
- delayed onset muscle soreness¹⁶
- function after total knee arthroplasty¹⁷
- healing time of primary burns and autologous donor sites¹⁸
- pain associated with temporomandibular joint (TMJ) disease^{19,20}
- palatal wound healing²¹
- post-operative pain for total hip arthroplasty²²
- rotator cuff tears²³
- subacromial impingement²⁴
- symptoms of advanced diabetes, including neuropathic pain, hypertension, and wound healing^{25,26}

- venous ulcers²⁷

All of the above RCTs listed above are limited by small study populations, which limit the ability to rule out spurious results and do not allow for generalizability. In addition, the studies above all reported short follow-up periods and suffered from other methodological limitations. For indications where more than one RCT had been published, results were conflicting and in some cases reported outcomes were no better than placebo.

CLINICAL PRACTICE GUIDELINES

American Physical Therapy Association (APTA)

The 2013 APTA guidelines on physical therapy management of congenital muscular torticollis stated that microcurrent may be considered as one of several possible supplemental interventions, but should only be applied by clinicians skilled in that modality.²⁸ This weak recommendation was based on one small comparative study of 15 patients.¹⁴

CENTERS FOR MEDICARE & MEDICAID

As 03/21/2021, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses microcurrent electrical nerve stimulation (MENS) for any indication.

POLICY SUMMARY

There is not enough evidence to show that microcurrent electrical nerve stimulation (MENS) is effective for any indication, compared to other treatment modalities. The body of evidence includes randomized controlled trials for a wide variety of indications that require either pain reduction or stimulation of the body's healing process. The RCTs all suffer from the same limitations, regardless of the indication evaluated. These limitations include: a small number of patients tested, diverse patient populations and different procedure protocols performed, and little to no follow-up with patients following treatment. Therefore, based on the lack of larger well-designed studies, conclusions cannot be reached about the effectiveness of MENS therapy. In addition, no clinical practice guidelines that perform a thorough review of evidence recommend the use of MENS .

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

U.S. Food & Drug Administration (FDA) Device Approval

Most microcurrent stimulators are categorized as transcutaneous electrical nerve stimulation (TENS) devices and are approved as 510(k) Class II devices equivalent to predicate TENS devices.²⁹ FDA Product code: GXY. Examples of FDA-approved devices include, but are not limited to:

- Alpha-Stim PPM (personal pain manager)
- Inspirstar ISO2 Microcurrent Stimulator (Inspirstar Inc.)
- Promax-MC, Microcurrent Device, Model MC-4440 (Rehabilitare, Inc.)

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

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