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Medical Policy Manual Medicine, Policy No. 143

Transcutaneous Electrical Modulation Pain Reprocessing

Effective: February 1, 2025

Next Review: October 2025
Last Review: December 2024

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

Transcutaneous electrical modulation, also known as scrambler or electrical neuromodulation therapy, is a pain treatment involving a sequence of treatments with electrical stimulation.

MEDICAL POLICY CRITERIA

Transcutaneous electrical modulation pain reprocessing (scrambler therapy, electrical neuromodulation) is considered **investigational** for the treatment of any indication.

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

CROSS REFERENCES

1. Functional Neuromuscular Electrical Stimulation, Durable Medical Equipment, Policy No. 83.04
2. Interferential Current Stimulation, Durable Medical Equipment, Policy No. 83.07
3. Electrical Stimulation and Electromagnetic Therapy for the Treatment of Arthritis, Durable Medical Equipment, Policy No. 83.10
4. Electromagnetic Therapy, Durable Medical Equipment, Policy No. 83.13
5. Percutaneous Neuromodulation Therapy (PNT), Surgery, Policy No. 44

BACKGROUND

Transcutaneous electrical modulation pain reprocessing (TEMPR), also called scrambler therapy, is intended to interrupt transmission of pain signals by delivering electrical stimulation that is interpreted by the nervous system as “no pain”. Scrambler therapy is performed using a type of transcutaneous electrical stimulation (TENS) device that is specifically designed for this therapy. Cutaneous nerves are stimulated using five surface electrode pairs (i.e., channels) that are placed in the dermatomes above and below the pain area.

Unlike conventional TENS, scrambler therapy is administered in the office setting under physician supervision. According to Competitive Technologies, Inc., the makers of Calmare® Pain Therapy device, “the physician provides the initial consultation to discern the most effective path for electrode placement. Treatment applications are interactive between the patient and the provider, with the provider attending and making adjustments approximately every 10 minutes throughout the treatment session, which typically lasts an hour.”

REGULATORY STATUS

The Calmare® Pain Therapy device (Competitive Technologies, Inc.) has 510k approval (K081255) from the U.S. Food and Drug Administration (FDA) under the name Scrambler Therapy MC-5A TENS Device.[1] The indications for the Scrambler Therapy MC-5A TENS Device are listed as: symptomatic relief of chronic, intractable pain, post-surgical and posttraumatic acute pain, symptomatic relief of acute pain, and symptomatic relief of post-operative pain.

The Nerivio® device (Theranica Bio-Electronics, LTD) has 510k approval (K203181) from the FDA for the indication: acute treatment of migraine with or without aura in patients 12 years of age or older. It is a prescription use, self-administered device for use in the home environment at the onset of migraine headache or aura.[2]

EVIDENCE SUMMARY

The most clinically relevant outcomes of therapy for intractable pain are improvements in pain and/or function. Both of these outcomes can be influenced by nonspecific effects, placebo response, natural history of the disease, and regression to the mean; therefore, these therapies need to be evaluated in randomized, controlled trials that maintain satisfactory blinding of the treatment assignment. The appropriate control for electrical stimulation devices for treatment of pain is sham treatment. Pain outcomes require quantifiable pre- and post-treatment measures, which are most commonly measured with a visual analogue scale (VAS). Collectively, the pain measurement literature cautions against using only statistical significance of difference in mean change in scores to determine clinical significance. More meaningful to patients and clinicians is the correlation of improvement in pain scores with improvement in function and quality of life. Thus, quantifiable pre- and post-treatment measures of functional status are also necessary.

SYSTEMATIC REVIEW

Wang (2023) published a systematic review to qualitatively synthesize all reported cases of complications, adverse effects, side effects, or harms arising from the use of scrambler therapy.[3] Six RCTs, 19 prospective open-label trials, and 11 case series were included with a total of 1,152 participants. Two patients experienced contact dermatitis, and one patient

reported minor ecchymosis that resolved without intervention. This yielded a composite complication rate of 0.26% (occurred in 3 out of 1,152 participants). No serious adverse events were reported. The authors concluded that scrambler therapy is associated with a lower composite outcome of serious adverse events than invasive neuromodulation devices (e.g., devices that require implantation).

Jin (2022) published a systematic review evaluating the efficacy of scrambler therapy for the management of chronic pain which included 287 patients across seven RCTs.[4] The primary outcome assessed was pain score and a marginal decrease was identified in the meta-analysis when comparing the treatment to a control group. The authors noted that scrambler therapy may show improvements in some populations, there was substantial heterogeneity in the included studies and they suffered from small sample sizes and low quality.

VanderPluym (2021) published a systematic review with meta-analysis of the benefits and harms associated with acute treatments for episodic migraine in adults.[5] The main outcomes included pain freedom, pain relief, sustained pain freedom, sustained pain relief, and adverse events. The strength of evidence (SOE) was graded with the Agency for Healthcare Research and Quality Methods Guide for Effectiveness and Comparative Effectiveness Reviews. For interventions other than NSAIDs or triptans, data from 115 randomized controlled trials (RCTs) with data from over 27,000 patients were evaluated. Eighteen RCTs (n=1751) evaluating nonpharmacologic therapies were included in the review. Compared to sham, remote electrical neuromodulation was significantly associated with improved freedom from pain (RR, 1.95 [95% CI, 1.19 to 3.19]) and pain relief at two hours (RR, 1.65 [95%CI, 0.04 to 0.24]) as well as sustained pain relief at one week (RR, 2.27 [95%CI 1.30 to 3.95]), all based on data from one RCT with 252 patients (Yarnitsky 2019), moderate strength of evidence (SOE).[6] Comparative effectiveness is limited, as no RCT comparing remote electrical neuromodulation to active therapy were identified.

An Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Review by Singh (2020) evaluated RCTs and comparative observational studies on pharmacologic and nonpharmacologic therapies for the acute treatment of episodic migraine in adults.[7] Seventeen RCTs and one comparative observational study (n=1,758) were included for the review specific to nonpharmacologic therapy, however, only one study, an RCT with 252 subjects (Yarnitsky 2019) evaluated remote electrical neuromodulation versus placebo.[6] While the study met all of its outcomes, including pain free at two hours, pain relief at two hours, and sustained pain relief at one week, the overall evidence strength for remote electrical neuromodulation for the treatment of acute migraine is moderate to low, with the rationale being imprecision or severe imprecision for all outcomes assessed, including those listed above. A key summary of the AHRQ review is “several nonpharmacological acute treatments of migraine may improve various measures of pain compared with placebo, although only studied in one or a few small trials” and “evidence was insufficient to draw conclusions about serious adverse events”.

Moisset (2020) published a systematic review with meta-analysis of RCTs evaluating migraine treatment using neurostimulation methods.[8] Outcomes were defined as two hours pain free for acute treatment and headache days per month for preventive treatment. Efficacy was assessed based on effect size or absolute difference between active and placebo or sham, or number needed to treat (NNT). Thirty-eight articles were included in the qualitative analysis (seven acute, 31 preventive) and 34 in the quantitative evaluation (six acute, 28 preventive). Two of the studies, which were conducted by a single group (Yarnitsky 2017[9] and Yarnitsky

2019[6]), evaluated remote electrical neuromodulation. The NNT was 5 in the smaller (2017) study and 3.6 in the larger higher-quality (2019) study. While the analysis of data from these two studies found a positive effect of remote electrical neuromodulation with a large effect size (RR=2.14, 95% CI: 1.34 to 3.40), it must be noted that the two studies included in the quantitative analysis were led by a single group. The longest duration follow-up for remote electrical neuromodulation was 48 hours post-treatment. The long-term benefits of remote electrical neuromodulation are yet to be proven.

Majithia (2016) published a systematic review evaluating scrambler therapy for the management of chronic pain.[10] A comprehensive literature search was conducted, and 20 studies were included of varying quality. In general, most of the studies reported positive findings but many of them were small, short-term, lacked a comparator group, and were not randomized. The authors concluded that additional larger, high-quality studies are needed to further evaluate this therapy.

RANDOMIZED CONTROLLED TRIALS

Additional RCTs not addressed in the systematic reviews are summarized here.

Stowell-Campos (2024) published a sham-controlled, participant-blinded RCT that assessed scrambler therapy for the treatment of post-stroke pain (n=20).[11] Average participant age was 60 years in the treatment group and 56.9 years in the sham group. The average time post-stroke was 35 months (treatment group) and 29.5 months (sham group). Participants received 40 minutes of active or sham therapy for five consecutive days. Pain scores, measured using a dermatomal map and Numerical Rating Scale (0-10), were obtained and recorded at baseline, prior to and after each treatment session, and again four weeks after treatment. Mean pain score decreased from 6.68 to 2.95 (56% reduction) in the scrambler therapy group and from 5.73 to 4.79 (16% reduction) in the sham group after five treatment sessions. Nine of 10 patients in the scrambler therapy group reported some improvement in pain score, while 7 of 10 patients in the sham group reported some benefit (p=0.264). Seven of 10 patients in the scrambler therapy group reported a >50% decrease in pain score, while only one patient in the sham group reported a >50% decrease (p=0.006). At four-week follow-up, mean pain score decreased from 6.68 to 4.11 (38% reduction) in the scrambler therapy group and decreased from 5.73 to 5.48 (4% reduction) in the sham group. Three patients in the scrambler therapy group reported a >50% decrease in pain score, while only one patient in the sham group reported a >50% decrease (p=0.264). This study is limited by small sample size and short follow-up.

Tepper (2023) published a double-blind, placebo-controlled, multi-center RCT to assess the clinical efficacy of remote electrical neuromodulation (REN), used every other day, for the prevention of migraine.[12] The study consisted of a four-week baseline observation phase and an eight-week intervention phase in which participants used either REN (n=95) or placebo (n=84) stimulation every other day. Participants reported symptoms daily in an electronic diary. REN was superior to placebo in the primary endpoint, change in mean number of migraine days per month from baseline, with mean reduction of 4.0 ± SD of 4.0 days (1.3 ± 4.0 in placebo, therapeutic gain=2.7 [confidence interval -3.9 to -1.5], p<0.001). REN was also superior to placebo in reduction of moderate and severe headache days (3.8 ± 3.9 vs. 2.2 ± 3.6, p=0.005), reduction of headache days of all severities (4.5 ± 4.1 vs. 1.8 ± 4.6, p<0.001), percentage of patients achieving 50% reduction in moderate/severe headache days (51.6% [49/95] vs. 35.7% [30/84], p=0.033), and reduction in days of acute medication intake (3.5 ±

4.1 vs. 1.4 ± 4.3, p=0.001). No severe adverse events were reported. This study is limited by short-term follow-up and lack of comparison to established pharmacological treatments for migraine.

A phase I RCT was published by Childs (2021) which evaluated the efficacy of scrambler therapy vs. TENS in treating chemotherapy-induced peripheral neuropathy (CIPN).[13] Fifty patients were recruited for the first half of a two-part, crossover trial consisting of a two-week treatment period with either scrambler or TENS, followed by an eight-week observation period, and then crossover treatment. Twenty-two patients proceeded to the crossover phase. A 50% or greater reduction in primary symptom (pain or tingling) score on the last day of treatment was achieved by 6 of 10 scrambler-treated patients (60%) and 3 of 12 TENS-treated patients (25%) after crossover (p=0.11). Evaluation in a larger, longer-term trial with standardized CIPN treatment is needed.

Smith (2019) reported outcomes from an RCT that compared scrambler therapy and sham for the treatment of CIPN.[14] Data were collected from 33 patients, with 17 and 18 in the treatment and sham groups, respectively. The primary outcome was reduction in pain scores. There was no difference in reduction in pain from baseline between groups at 28 days (p=0.8). Statistically significant changes in sensory scores and motor scores were reported for both groups. No significant differences between groups were reported.

Loprinzi (2019) published another RCT of treatments for CIPN. This study compared the efficacy of scrambler therapy and transcutaneous electrical nerve stimulation (TENS).[15] A total of 50 patients were randomized to receive scrambler therapy or TENS for two weeks. Data were reported from 46 patients. Patient-reported outcomes, collected during the two weeks of treatment and the eight following weeks, were used as the measure of efficacy and toxicity. The primary endpoint was 50% or greater reduction in pain/tingling scores. At the end of the two weeks of treatment, this was achieved in 40% of the scrambler group and 20% of the TENS group (p=0.12). Overall, during the two weeks of treatment, the scrambler-treated patients reported 36 to 56% reductions from baseline in pain, tingling, and numbness, and the reductions in these same measures in the TENS-treated patients were 16 to 28%. No severe adverse events were reported.

Starkweather (2015) published the results of a double-blind RCT which evaluated the effects of the scrambler therapy on lower back pain intensity.[16] A total of 30 participants were randomized to receive up to 10 sessions of Calmare® (n=15) or sham (n=15) and followed for three weeks. Pain intensity was measured using the Brief Pain Inventory-Short Form. Although the authors reported a significant decrease in the “worst” pain compared to the sham group, this study contains numerous methodological limitations including but not limited to small sample size and short-term follow-up which limit conclusions regarding the benefits of scrambler therapy.

Marineo (2012) published a small, randomized, short-term pilot study that compared scrambler therapy with pain medication in 55 patients matched for type of pain which included postoperative neuropathic pain, postherpetic neuralgia, or spinal canal stenosis.[17] The authors reported significantly greater pain reduction in the scrambler therapy group compared with the medication control group at one-, two-, and three-month follow-up. While this study is useful in informing hypothesis formation, it does not permit conclusions on efficacy and safety due to small size, lack of a sham control group, and short-term followup period.

NONRANDOMIZED STUDIES

The remaining published trials are limited to nonrandomized studies.[18-41] Evidence from these studies does not permit conclusions due to methodological limitations, such as non-random allocation of treatment, non-blinded study design, and lack of comparison groups.

PRACTICE GUIDELINE SUMMARY

DEPARTMENT OF VETERANS AFFAIRS/DEPARTMENT OF DEFENSE

The U.S Department of Veterans Affairs/Department of Defense (VA/DoD) 2023 guidelines for the management of headache state that "there is insufficient evidence to recommend for or against any form of neuromodulation for the treatment and/or prevention of migraine"; examples of neuromodulation treatments mentioned include remote electrical neurostimulation.[42]

SUMMARY

There is not enough research to show whether transcutaneous electrical modulation (neuromodulation) pain reprocessing (i.e., scrambler therapy) is an effective treatment for pain from any cause. Further, there are no evidence-based clinical practice guidelines that recommend scrambler therapy. Therefore, transcutaneous electrical modulation pain reprocessing therapy is considered investigational for all indications.

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2. US Food and Drug Administration Nerivio 510(k) approval K203181. [cited 11/25/2024]. 'Available from:' https://www.accessdata.fda.gov/cdrh_docs/pdf20/K203181.pdf.
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CODES

Codes	Number	Description
CPT	0278T	Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)
HCPCS	A4540	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm

Date of Origin: *November 2011*