

Transcutaneous Electrical Modulation Pain Reprocessing

Effective: November 1, 2018

Next Review: October 2019

Last Review: October 2018

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

“Scrambler therapy” is a pain treatment involving a sequence of treatments with electrical stimulation in the office setting.

MEDICAL POLICY CRITERIA

Transcutaneous electrical modulation pain reprocessing (scrambler therapy) is considered **investigational** for the treatment of acute or chronic pain, including but not limited to the following:

- A. Arthritis (any type)
- B. Back and neck pain, chronic or acute
- C. Cancer pain
- D. Chemotherapy-related pain
- E. Musculoskeletal pain
- F. Neuropathic pain
- G. Pain syndromes [e.g., complex regional pain syndrome (CRPS); reflex sympathetic dystrophy (RSD)]

- H. Post-operative pain
- I. Traumatic injury
- J. Visceral pain

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. [Percutaneous Neuromodulation Therapy \(PNT\)](#), Surgery, Policy No. 44
5. [Peripheral Subcutaneous Field Stimulation](#), Surgery, Policy No. 188

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 (K081258) from the U.S. Food and Drug Administration (FDA) under the name Scrambler Therapy MC-5A TENS Device.

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

Majithia (2016) published a systematic review evaluating scrambler therapy for the management of chronic pain.^[1] 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

In 2015, Starkweather, published the results of a double-blind RCT which evaluated the effects of the scrambler therapy on lower back pain intensity.^[2] A total of 30 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.

The second published RCT, from Marineo (2012), is a small, 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.^[3] 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 RCT 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.^[4-20] Evidence from these studies is 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

There are no clinical guidelines from professional associations that recommend scrambler therapy.

SUMMARY

There is not enough research to show the benefits of transcutaneous electrical modulation pain reprocessing (i.e., scrambler therapy) as a 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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CODES

Codes	Number	Description
CPT	0278T	Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy), each treatment session (includes placement of electrodes)
HCPCS	None	

Date of Origin: November 2011