Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 9/1/24**
(See policy history boxes for previous effective dates)

Title: Transcutaneous Electrical Modulation Pain Reprocessing (Scrambler Therapy)

Description/Background

Transcutaneous electrical modulation pain reprocessor therapy (also referred to as TEMPR, Calmare® Pain Therapy or Scrambler Therapy™), is a proposed method for treating pain. Scrambler Therapy uses biophysical stimulation rather than biochemical pain suppression. The Calmare device uses surface electrodes to send continuously-varying electrical impulses along the same nerve pathways that are transmitting the pain stimulus. The theoretical mechanism is that the C fibers that sense chronic pain will be interrupted, or scrambled, by the new signal, and the pain information is replaced with artificial “non-pain” information. Pain transmission is not inhibited but is transformed. Although the focus of Scrambler Therapy is chronic pain, it has also been FDA-approved for the treatment of acute pain. (See Regulations section.)

Scrambler Therapy is performed in a physician’s office. Electrodes are placed on the dermatome above and below the area of pain. The treatment outcome is purported to be highly dependent on the operator’s ability to correctly identify electrode positioning areas and to fine-tune stimulation intensity. The key to the pain system remodulation process is the ability to achieve a pain rating of 2/10 or less during each treatment session, without the patient feeling any significant discomfort from the stimulation. Typical treatment includes daily sessions of about 30-45 minutes for two consecutive weeks, with occasional booster sessions for relapse.[1]

Regulatory Status:

The Scrambler Therapy MC-5A TENS Device* (Competitive Technologies, Inc.) received FDA clearance as substantially equivalent to previously marketed TENS devices on February 20, 2009 (K081255.) The device is indicated for symptomatic relief of chronic, intractable pain,

post-surgical and posttraumatic acute pain; symptomatic relief of acute pain; symptomatic relief of post-operative pain.[2]

A second 510(k) clearance (K142666) was issued on May 22, 2015, for Scrambler Therapy MC-5 A Device (Delta International Service & Logistics S.r.l.).[3]

*Scrambler Therapy is also known as the Calmare® Pain Therapy device.

Medical Policy Statement

The effectiveness of transcutaneous electrical modulation pain reprocessor therapy for the treatment of pain has not been established, therefore, it is considered experimental/ investigational.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0278T

Rationale

Clinically relevant outcomes of therapies for chronic pain include improvements in level of pain or function. Therapies need to be evaluated in randomized, controlled trials that maintain blinding of the treatment assigned. The appropriate control for electrical stimulation devices is sham treatment. Additionally, quantifiable pre- and post-treatment measures of functional status are also vital.

The developers of Scrambler Therapy have touted its positive effect on chronic pain of various etiologies; however, they particularly market the device for relief of chronic neuropathic pain.

SYSTEMATIC REVIEWS
Kashyap and Bhatnagar (2020) reviewed the literature to determine the efficacy of scrambler therapy for cancer pain that is resistance to pharmacologic management.[4] Twenty-seven studies were retrieved. Ten articles, categorized as literature reviews, included 7 general literature reviews not following a specific review methodology, 1 editorial, and 2 systematic reviews. Seventeen were original studies, including 2 single-arm trials, 1 randomized

controlled trial, 4 pilot trials, 4 case reports, 2 retrospective studies, and 4 prospective studies. Overall, the available literature supports the use of scrambler therapy for the management of refractory cancer pain. The reviewers stated that the level of evidence for scrambler therapy's application to cancer pain is not particularly strong, and improvement in pain with scrambler therapy may be owing to a placebo effect. Due to the limited number of clinical trials on scrambler therapy in cancer pain, a meta-review could not be performed. The reviewers concluded that methodologically sound, large, randomized control trials are needed in this area.

Majithia et al (2016) performed a review to evaluate the mechanisms and mechanics of Scrambler Therapy and to investigate data pertaining to its efficacy.[5] At the time of the review, 20 reports were published; all but one small study provided results that appeared positive. The reviewers concluded that the findings of the preliminary studies supported the device's benefit. They also recommended larger, randomized studies to further evaluate Scrambler Therapy's efficacy. Of note, it was disclosed that several of the reviewers/authors utilized Scrambler Therapy in their clinical practices.

RANDOMIZED CONTROLLED TRIALS

Nayback-Beebe et al (2020) reported on the effectiveness of Calmare Scrambler Therapy in military service members with chronic neuropathic pain symptoms.[6] Forty-seven participants were randomized to receive ten 30-minute active ST or sham treatments. Data were collected at baseline, posttreatment, and 1-month follow-up. The authors reported that the groups showed no statistically significant differences in pain scores, medication use, or mental or physical health-related quality of life with active versus sham treatment. However, both groups experienced clinically meaningful reductions in pain and improvements in physical health-related quality posttreatment that was sustained at 1-month follow-up. Ninety percent of the blinded sample described the treatment intervention as a partial or complete success. The authors concluded that ST was no better than sham treatment in decreasing pain.

Mealy et al (2020) reported on the use of Scrambler therapy as a treatment of persistent central neuropathic pain in patients with neuromyelitis optica spectrum disorder.[7] Pain severity, pain interference, anxiety, depression, and sleep disturbance were assessed at baseline, at the end of treatment, and at the 30- and 60-day follow-up. Twenty-two patients (11 per arm) were enrolled in and completed this trial. The median baseline numeric rating scale (NRS) pain score decreased from 5.0 to 1.5 after 10 days of treatment with Scrambler therapy, whereas the median NRS score did not significantly decrease in the sham arm. The authors reported that depression was reduced in the treatment arm, and anxiety was decreased in a subset of patients who responded to treatment. These symptoms were not affected in the sham arm. The authors concluded that Scrambler therapy is an effective, feasible, and safe intervention for central neuropathic pain in patients with NMOSD.

Smith et al (2019) reported on a randomized sham-controlled Phase II trial of Scrambler Therapy.[8] Thirty-five patients with chemotherapy-induced peripheral neuropathy received ten 30-minute sessions of ST on the dermatomes above the painful areas, or sham treatment on the back, typically at L3-5 where the nerve roots enter the spinal cord. The primary end point was "average pain" after 28 days on the Numeric Rating Scale. Outcomes included the Brief Pain Inventory Chemotherapy-Induced Peripheral Neuropathy (BPI CIPN) and the European Organization of Research and Treatment of Cancer Chemotherapy-Induced Peripheral Neuropathy (EORTC CIPN-20) scale. Patients were evaluated before treatment (day 0), day

10, and days 28, 60, and 90. Data regarding pain as a primary outcome were collected for 33 of the 35 patients. There were no significant differences between the sham and the “real” ST group at day 10, 28, 60, or 90, for average pain, the BPI, or EORTC CIPN-20. There was improvement in the sensory subscale of the CIPN-20 at 2 months in the “real” group (P =.14). All “real” patients wanted to continue treatment if available. This study found no difference between sham and real ST CIPN treatment.

Loprinzi et al (2019) reported on a pilot study of 50 patients with chemotherapy-induced peripheral neuropathy, whose symptoms were present for at least 3 months, and who rated pain or tingling at least 4/10 in severity in the week prior to registration.[9] Half were randomized to Scrambler Therapy, the other half to transcutaneous electrical nerve stimulation for 2 weeks. Patient-report outcomes were measured daily for 2 weeks, then weekly for an additional 8 weeks. Of the initial cohort, 46 were evaluable. The authors reported that twice as many Scrambler-treated patients had at least 50% documented improvement during the 2 treatment weeks when compared to the TENS-treated patients. The authors reported positive results and supported further studies of Scrambler Therapy for CIPN.

Starkweather et al (2015) reported on a clinical trial (NCT01896687) of Calmare for low back pain.[10] Thirty participants were randomized to receive up to 10 sessions of Calmare treatment (n=15) or a sham treatment (n=15) using the same device at a non-therapeutic threshold. At 3 weeks after conclusion of treatment, the Calmare group reported a significant decrease in the "worst" pain and interference scores. There were also significant differences in pain sensitivity and differential mRNA expression of 17 pain genes, suggesting that Calmare can be effective in reducing pain intensity and interference in individuals with persistent low back pain by altering the mechanisms of enhanced pain sensitivity. The authors recommended further study of long-term pain outcomes, particularly functional status, analgesic use and health care utilization.

Marineo et al (2012), in a pilot randomized trial, compared pharmacological treatment to Scrambler Therapy in 52 patients with conditions of postsurgical neuropathic pain, postherpetic neuralgia or spinal canal stenosis.[11] Primary outcome was change in visual analogue scale (VAS) pain scores at one month; secondary outcomes included VAS pain scores at two and three months, pain medication use, and allodynia. The mean VAS pain score before treatment was 8.1 points (control) and 8.0 points (Scrambler). At one month, the mean VAS score was reduced from 8.1 to 5.8 (-28%) in the control group, and from 8 to 0.7 points (-91%) in the Scrambler group (P<.0001). At two and three months, the mean pain scores in the control group were 5.7 and 5.9 points, respectively, and 1.4 and 2 points in the Scrambler group, respectively (P<.0001). The authors concluded that Scrambler Therapy appeared to relieve chronic neuropathic pain more effectively than guideline-based drug management.

NONRANDOMIZED STUDIES

There are numerous single-arm or observational studies that have been published, testing a wide range of conditions, including visceral pain, chronic pain syndromes, chemotherapy-induced neuropathy, traumatic injury, post-operative pain, musculoskeletal pain, arthritis, neuropathic pain and cancer pain. However, due to methodological limitations, evidence from these reviews does not permit conclusions.

Summary of Evidence

A systematic review in 2020 stated that improvement in cancer pain with scrambler therapy might be owing to a placebo effect and recommended that large RCTs are needed. A systematic review in 2016 concluded that there was benefit to Scrambler Therapy. The reviewers recommended further research. It was noted that several of the authors/reviewers used Scrambler Therapy in their clinical practices.

Six RCTs were identified that evaluated Scrambler Therapy. Two found no better outcomes for Scrambler Therapy than for the control groups. The remaining four reported Scrambler effectiveness. A limitation of these studies is the relatively small study sizes. Additionally, the etiologies of pain vary, which makes comparison and validation difficult. Scrambler Therapy has been reported to be an operator-dependent methodology, effectively making significant, consistent results difficult to reproduce with a novice operator. While Scrambler Therapy may be safe, its effectiveness has not been proven.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

There are no guidelines found recommending the Calmare® device for pain management.

Clinical Trials

Ongoing clinical trials that may impact this review are listed below.

Table 1. Summary of Key Trials

NCT number	Trial Name	Planned Enrollment	Completion Date
Completed			
NCT02722434	MC5-A Scrambler Therapy or TENS Therapy in Treating Patients with Chemotherapy-Induced Peripheral Neuropathy (Mayo Clinic)	50	Jan 12, 2022
Unknown			
NCT03865693	Effects of Pain Scrambler Therapy for the Alterations of Cerebral Blood Volume in Pain Network of Neuropathic Pain on Burn Patients (Korea)	40	Nov 2020 (last update June 2019) (results unknown)

Government Regulations

National:

There is no national coverage determination for transcutaneous electrical modulation pain reprocessing (Scrambler Therapy).

Local:

There is no local coverage determination for transcutaneous electrical modulation pain reprocessing (Scrambler Therapy).

Wisconsin Physicians Service Insurance Corporation [08202] MAC Part B (J8) – MI
Local Coverage Article: Billing and Coding: Category III Codes (A56902)
Original Effective Date: 08/29/2019
Revision Effective Date: 03/28/2024
0278T is not listed as a code that is reasonable and medically necessary.

There is no fee found on the CMS 2024 Physician Fee Schedule for 0278T.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Interferential Stimulation (Sympathetic Therapy)
- Microcurrent Electrical Neurostimulation (MENS) for Home Use (e.g., AlphaStim® PPM) (Retired)
- Neuromuscular Electrical Stimulation (NMES) (Retired)
- Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)
- Sacral Nerve Neuromodulation/Stimulation
- Transcutaneous Electric Nerve Stimulator (TENS) (BCN Only) - Retired

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References

1. Marineo G. Inside the scrambler therapy, a noninvasive treatment of chronic neuropathic and cancer pain: from the gate control theory to the active principle of information. Integrative Cancer Therapies, Vol 18:1-17. 2019.
2. U.S. Food and Drug Administration. 510(k) Summary, Scrambler Therapy MC-5A TENS Device (Competitive Technologies, Inc.). K081255. February 20, 2009.
3. U.S. Food and Drug Administration. 510(k) Summary, Scrambler Therapy MC-5A Device (Delta International Service & Logistics s.r.l.). K142666. May 22, 2015.
4. Kashyap K, Bhatnagar S. Evidence for the efficacy of scrambler therapy for cancer pain: a systematic review. Pain Physician. 2020 Jul;23(4):349-364, PMID 32709170
5. Majithia N, et al. Scrambler Therapy for the management of chronic pain. Support Care Cancer. 2016;24(6):2807-2814.
6. Nayback-Beebe A, Panula T, Arzola S, Goff B. Scrambler therapy treatment: the importance of examining clinically meaningful improvements in chronic pain and quality of life. Mil Med. 2020;185(Suppl 1):143-147.
7. Mealy AM, et al. Scrambler therapy improved pain in neuromyelitis optica: a randomized controlled trial. Neurology. 2020 May 5;94(18):e1900-1907.
8. Smith T J, et al. A Pilot Randomized Sham-Controlled Trial of MC5-A Scrambler Therapy in the Treatment of Chronic Chemotherapy-Induced Peripheral Neuropathy (CIPN). Journal of Palliative Care. Jan 1, 2019.

9. Loprinzi C, et al. Scrambler therapy for chemotherapy neuropathy: a randomized phase II pilot trial. Supportive care in cancer: official journal of the Multinational Association of Supportive Care in Cancer. 2019.
10. Starkweather AR, et al. Decreased low back pain intensity and differential gene expression following Calmare®: results from a double-blinded randomized sham-controlled study. Research in nursing & health. 2015 Feb;38(1):29-38.
11. Marineo G, et al. Scrambler therapy may relieve chronic neuropathic pain more effectively than guideline-based drug management: results of a pilot, randomized, controlled trial. J Pain Symptom Manage. 2012 Jan;43(1):87-95. PMID: 21763099
12. Wisconsin Physicians Service Insurance Corporation. Local Coverage Article: Billing and Coding: Category III Codes (A56902). Revision effective date 03/28/2024

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 4/8/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/12	2/21/12	2/21/12	Joint policy established
5/1/13	2/19/13	3/4/13	Routine maintenance
9/1/15	6/19/15	7/16/15	Routine maintenance
9/1/16	6/21/16	6/21/16	Routine maintenance
9/1/17	6/20/17	6/20/17	Routine maintenance
9/1/18	6/19/18	6/19/18	Routine maintenance
9/1/19	6/18/19		Routine maintenance
9/1/20	6/16/20		Routine maintenance; background, rationale updated.
9/1/21	6/15/21		Routine maintenance
9/1/22	6/21/22		Routine maintenance Ref 4 added
9/1/23	6/13/23		Routine maintenance (jf) Vendor Managed NA
9/1/24	6/11/24		Routine maintenance (jf) Vendor Managed NA

Next Review Date: 2nd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: TRANSCUTANEOUS ELECTRICAL MODULATION PAIN REPROCESSING (SCRAMBLER THERAPY)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not Covered.
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.