



An Independent Licensee of the Blue Cross Blue Shield Association

**EVIDENCE-BASED CRITERIA**  
**SECTION: Durable Medical Equipment (DME)**

**ORIGINAL EFFECTIVE DATE: 12/06/22**  
**LAST REVIEW DATE: 12/06/22**  
**CURRENT EFFECTIVE DATE: 12/06/22**  
**LAST CRITERIA REVISION DATE: 12/06/22**  
**ARCHIVE DATE:**

**NEXT ANNUAL REVIEW DATE: 4TH QTR 2023**

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## **ELECTRICAL STIMULATION**

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**Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.**

**Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.**

**This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.**

**The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.**

**The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.**

**State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.**

**Evidence-Based Criteria are subject to change as new information becomes available.**

**For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.**

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## **ELECTRICAL STIMULATION (cont.)**

### **Description:**

#### Accelerated Recovery Performance ARPwave™:

ARPwave consists of a table top electrical generator with software controlled parameters and electrodes. It has been investigated to both determine the specific sites where treatment is needed and to deliver treatment. Direct electrical current and a patented bioelectrical current are used simultaneously with exercise techniques for rehabilitation following surgery and for pain treatment.

#### Form-Fitting Conductive Garment:

Customized body-contoured garment for electrical stimulation. All electrodes and lead wires are sewn into the garment to simplify lead placement and minimize setup time.

#### High Voltage Galvanic Stimulation (HVGS):

An interrupted, pulsed direct current that causes electrochemical changes at the cellular level. The cellular changes cause reflex vasodilation that may be effective in controlling localized pain. HVGS is also known as High Voltage Pulsed Current (HVPC), Electro-galvanic Stimulation, or Hi-Volt.

#### Micro Current Therapy™:

Micro current therapy, also known as microcurrent electrical neuromuscular stimulation (MENS), is a small, 'band-aid' sized device attached directly to the skin over the intended treatment area. Once activated, produces a low amperage, pulsating electrical current that radiates into the affected area, attracting blood and oxygen to the injured part and stimulating the body's healing process.

#### Rebuilder® System:

A transcutaneous nerve and muscle stimulator that has been investigated for pain relief by opening nerve pathways, causing muscles to contract and relax and stimulating the brain to release endorphins. Consists of controller and electrode pads that are placed directly on affected area.

#### Sympathetic Therapy:

Delivers electrical current via four electrodes placed strategically on the lower legs and feet, or on the arms and hands. The electrodes access the autonomic nervous system through the peripheral nerves with the intent of altering or masking the perception of chronic systemic pain. Known as Dynatron STS® and Dynatron STS® Rx Therapy System.

#### Transcutaneous Electrical Modulation Pain Reprocessing (TEMPR):

TEMPR, also known as Scrambler Therapy®, is a multi-channel electrical stimulation device that allows simultaneous treatment of a number of pain sites. Stimulation impulses are generated and controlled according to a stored program to provide pain relief by interrupting transmission of pain signals by delivering electrical stimulation that is interpreted by the nervous system as no pain.



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## **ELECTRICAL STIMULATION (cont.)**

### **Description:** (cont.)

#### Transcutaneous Electrical Modulation Pain Reprocessing (TEMPR): (cont.)

Treatment involves the initial physician consultation to discern the most effective electrode placement points followed by interactive physician-supervised treatment sessions that typically last one hour. Treatment is administered in the physician office setting under direct supervision to treat neuropathic pain, including pain associated with chemotherapy-induced peripheral neuropathy. Devices include, but are not limited to, CALMARE® device.

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### **Criteria:**

- High Voltage Galvanic Stimulation (HVGS) is considered **medically necessary** with documentation of **ANY** of the following:
  1. Symptomatic relief of chronic (3 months or greater), intractable, localized pain
  2. Management of post-surgical localized pain when oral or intravenous medications have failed to control pain or are contraindicated
  3. Management of post-traumatic, acute, localized pain
- High Voltage Galvanic Stimulation (HVGS) for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, *but are not limited to:*

- Labor and vaginal delivery pain relief
- Treatment of dementia
- Treatment of edema
- Treatment of swelling



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## ELECTRICAL STIMULATION (cont.)

### Criteria: (cont.)

- Accelerated Recovery Performance ARPwave therapy is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.
- Micro Current Therapy (MCT Patch) is available as an over-the-counter device and is, therefore, considered a **benefit plan exclusion** and **not eligible for coverage**.
- Rebuilder System for home use that is obtainable without a prescription is considered a **benefit plan exclusion** and **not eligible for coverage** as durable medical equipment under the medical benefit.
- Rebuilder System is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.
- Sympathetic Therapy is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

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## **ELECTRICAL STIMULATION (cont.)**

### **Criteria: (cont.)**

- Transcutaneous Electrical Modulation Pain Reprocessing (TEMPR) for all indications is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

### **Resources:**

**Literature reviewed 12/06/22. We do not include marketing materials, poster boards and non-published literature in our review.**

**Resources prior to 12/06/22 may be requested from the BCBSAZ Medical Policy and Technology Research Department.**

1. Al-Atiyat N, Obaid A. Management of peripheral neuropathy induced by chemotherapy in adults with cancer: a review. *International journal of palliative nursing*. Jan 2 2017;23(1):13-17. doi:10.12968/ijpn.2017.23.1.13
2. Childs DS, Le-Rademacher JG, McMurray R, et al. Randomized Trial of Scrambler Therapy for Chemotherapy-Induced Peripheral Neuropathy: Crossover Analysis. *J Pain Symptom Manage*. Jun 2021;61(6):1247-1253. doi:10.1016/j.jpainsymman.2020.11.025
3. Congedi S, Spadini S, Di Pede C, et al. Use of Scrambler Therapy in Acute Paediatric Pain: A Case Report and Review of the Literature. *Case reports in pediatrics*. 2016;2016:2628919. doi:10.1155/2016/2628919
4. D'Amato SJ, Mealy MA, Erdek MA, Kozachik S, Smith TJ. Scrambler Therapy for the Treatment of Chronic Central Pain: A Case Report. *A & A case reports*. Dec 28 2017;doi:10.1213/xa.0000000000000695
5. Jin Y, Kim D, Hur J, Myung SK. Efficacy of Scrambler Therapy for Management of Chronic Pain: A Meta-Analysis of Randomized Controlled Trials. *Pain Physician*. Oct 2022;25(7):E931-e939.
6. Joo SY, Cho YS, Cho SR, Kym D, Seo CH. Effects of pain Scrambler therapy for management of burn scar pruritus: A pilot study. *Burns : journal of the International Society for Burn Injuries*. Oct 15 2016;doi:10.1016/j.burns.2016.09.028

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## **ELECTRICAL STIMULATION (cont.)**

### **Resources: (cont.)**

7. Karri J, Marathe A, Smith TJ, Wang EJ. The Use of Scrambler Therapy in Treating Chronic Pain Syndromes: A Systematic Review. *Neuromodulation*. Jun 9 2022;doi:10.1016/j.neurom.2022.04.045
8. Kashyap K, Joshi S, Vig S, Singh V, Bhatnagar S. Impact of Scrambler Therapy on Pain Management and Quality of Life in Cancer Patients: A Study of Twenty Cases. *Indian journal of palliative care*. Jan-Mar 2017;23(1):18-23. doi:10.4103/0973-1075.197948
9. Kashyap K, Singh V, Mishra S, Dwivedi SN, Bhatnagar S. The Efficacy of Scrambler Therapy for the Management of Head, Neck and Thoracic Cancer Pain: A Randomized Controlled Trial. *Pain Physician*. Sep 2020;23(5):495-506.
10. Kashyap K, Singh V, Dwivedi SN, Gielen J, Bhatnagar S. Scrambler Therapy Enhances Quality of Life in Cancer Patients in a Palliative Care Setting: A Randomised Controlled Trial. *Indian journal of palliative care*. Jul-Sep 2022;28(3):287-294. doi:10.25259/ijpc\_94\_2021
11. Kim YN, Lee DK, Lee HJ. Effect of pain scrambler therapy on antineuralgic pain and quality of life after shingles. *Journal of physical therapy science*. Jun 2017;29(6):1113-1115. doi:10.1589/jpts.29.1113
12. Lee DK, Kim EK. Effect of pain scrambler therapy on shoulder joint pain and range of motion in patients who had undergone arthroscopic rotator cuff repair for the first time. *Journal of physical therapy science*. Jul 2016;28(7):2175-7. doi:10.1589/jpts.28.2175
13. Lee SC, Park KS, Moon JY, et al. An exploratory study on the effectiveness of "Calmare therapy" in patients with cancer-related neuropathic pain: A pilot study. *European journal of oncology nursing : the official journal of European Oncology Nursing Society*. Apr 2016;21:1-7. doi:10.1016/j.ejon.2015.12.001
14. Lee SY, Park CH, Cho YS, et al. Scrambler Therapy for Chronic Pain after Burns and Its Effect on the Cerebral Pain Network: A Prospective, Double-Blinded, Randomized Controlled Trial. *J Clin Med*. Jul 22 2022;11(15)doi:10.3390/jcm11154255
15. Loprinzi C, Le-Rademacher JG, Majithia N, 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*. Mar 2020;28(3):1183-1197. doi:10.1007/s00520-019-04881-3
16. Loprinzi CL. Prevention and treatment of chemotherapy-induced peripheral neuropathy. In: Savarese DMF, ed. *UpToDate*. UpToDate; 2022. Accessed November 14, 2022. <https://www.uptodate.com/contents/prevention-and-treatment-of-chemotherapy-induced-peripheral-neuropathy>

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## **ELECTRICAL STIMULATION (cont.)**

### **Resources:** (cont.)

17. Majithia N, Smith TJ, Coyne PJ, et al. Scrambler Therapy for the management of chronic pain. *Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer*. Jun 2016;24(6):2807-14. doi:10.1007/s00520-016-3177-3
18. Marineo G, Iorno V, Gandini C, Moschini V, Smith TJ. 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*. Jul 13 2011;doi:10.1016/j.jpainsymman.2011.03.015
19. Mealy MA, Kozachik SL, Cook LJ, et al. Scrambler therapy improves pain in neuromyelitis optica: A randomized controlled trial. *Neurology*. May 5 2020;94(18):e1900-e1907. doi:10.1212/WNL.00000000000009370
20. Michlovitz SL, Smith W, Watkins M. Ice and high voltage pulsed stimulation in treatment of acute lateral ankle sprains\*. *J Orthop Sports Phys Ther*. 1988 9(9):301-4. Abstract.
21. Murphy T, Erdek M, Smith TJ. Scrambler Therapy for the Treatment of Pain in Schwannomatosis. *Cureus*. Mar 2022;14(3):e23124. doi:10.7759/cureus.23124
22. Murphy TK, Pardo CA, Roda RH, Stone RL, Smith TJ. Successful Treatment of Paraneoplastic Neuropathy and Pruritis With Scrambler Therapy: A Case Report. *Cureus*. Jul 2022;14(7):e26861. doi:10.7759/cureus.26861
23. 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*. Jan 7 2020;185(Suppl 1):143-147. doi:10.1093/milmed/usz253
24. Nelson RM, Hayes KW, Currier DP. *Clinical Electrotherapy*. 3rd ed. Appleton & Lange; 1999.
25. Park HS, Kim WJ, Kim HG, Yoo SH. Scrambler therapy for the treatment of neuropathic pain related to leukemia in a pediatric patient: A case report. *Medicine*. Nov 2017;96(45):e8629. doi:10.1097/md.00000000000008629
26. Polak A, Kucio C, Kloth LC, et al. A Randomized, Controlled Clinical Study to Assess the Effect of Anodal and Cathodal Electrical Stimulation on Periwound Skin Blood Flow and Pressure Ulcer Size Reduction in Persons with Neurological Injuries. *Ostomy Wound Manage*. Feb 2018;64(2):10-29.
27. Prevost J, Lambert J. TENS and EMS Treatment for Diabetic Peripheral Neuropathy. *Altern Ther Health Med*. Sep 2022;28(6):57-59.
28. Raucci U, Tomasello C, Marri M, Salzano M, Gasparini A, Conicella E. Scrambler Therapy((R)) MC-5A for Complex Regional Pain Syndrome: Case Reports. *Pain practice : the official journal of World Institute of Pain*. Sep 2016;16(7):E103-9. doi:10.1111/papr.12474



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## **ELECTRICAL STIMULATION (cont.)**

### **Resources:** (cont.)

29. Smith T, Cheville AL, Loprinzi CL, Longo-Schoberlein D. Scrambler Therapy for the Treatment of Chronic Post-Mastectomy Pain (cPMP). *Cureus*. Jun 21 2017;9(6):e1378. doi:10.7759/cureus.1378
30. Smith TJ, Auwaerter P, Knowlton A, Saylor D, McArthur J. Treatment of human immunodeficiency virus-related peripheral neuropathy with Scrambler Therapy: a case report. *International journal of STD & AIDS*. Jun 21 2016;doi:10.1177/0956462416656688
31. Smith TJ, Razzak AR, Blackford AL, et al. A Pilot Randomized Sham-Controlled Trial of MC5-A Scrambler Therapy in the Treatment of Chronic Chemotherapy-Induced Peripheral Neuropathy (CIPN). *J Palliat Care*. Jan 2020;35(1):53-58. doi:10.1177/0825859719827589
32. Strada EA, Portenoy RK. Psychological, rehabilitative, and integrative therapies for cancer pain. In: Savarese DMF, ed. *UpToDate*. UpToDate; 2021. Accessed November 14, 2022. <https://www.uptodate.com/contents/psychological-rehabilitative-and-integrative-therapies-for-cancer-pain>
33. Stralka SW, Jackson JA, Lewis AR. Treatment of hand and wrist pain. A randomized clinical trial of high voltage pulsed, direct current built into a wrist splint. *AAOHN J*. 1998 May 46(5):233-6. Abstract.
34. Verma R, Shivadeva M, Bhupal DP, Veluswamy SK. Looking beyond the obvious: Role of non-invasive electroanalgesia in management of cancer pain. *Indian J Cancer*. Apr-Jun 2022;59(2):282-287. doi:10.4103/ijc.IJC\_1340\_20
35. Wang EJ, Berninger LE, Pantelyat AY, Hunsberger JB, Smith TJ. Scrambler Therapy for the Treatment of Multiple System Atrophy-Parkinsonian Subtype Pain: A Case Report. *A A Pract*. Jan 18 2022;16(1):e01560. doi:10.1213/xa.0000000000001560
36. Warner NS, Watson JC, Bendel MA, Moeschler SM. Refractory Pain Management in Amyloid-Associated Peripheral Neuropathy. *Regional anesthesia and pain medicine*. Jan 17 2018;doi:10.1097/aap.0000000000000733

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### **Coding:**

CPT: 0278T, 97014, 97032  
HCPCS: A9900, E1399, G0283





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<b><u>History:</u></b>	<b><u>Date:</u></b>	<b><u>Activity:</u></b>
Medical Policy Panel	12/06/22	Approved guideline
Legal Division	11/17/22	Review with no revisions

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### **Policy Revisions:**



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## **ELECTRICAL STIMULATION (cont.)**

### **Non-Discrimination Statement:**

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, [crc@azblue.com](mailto:crc@azblue.com). You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

### **Multi-Language Interpreter Services:**

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinigií Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éi doodago Háida bíjá anilyeedigií t'áadoo le'é yina'idilkidgo beehaz'ánii hólo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

