



MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 01/08/14
LAST REVIEW DATE: 01/22/19
LAST CRITERIA REVISION DATE: 09/01/16
ARCHIVE DATE:

ELECTRICAL STIMULATION

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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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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.

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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ELECTRICAL STIMULATION (cont.)

Criteria:

For treatment of arthritis, see BCBSAZ Medical Coverage Guideline #O876, *“Electrical Stimulation for Treatment of Arthritis”*.

For interferential current stimulation, see BCBSAZ Medical Coverage Guideline #O875, *“Interferential Current Stimulation”*.

For neuromuscular electrical stimulation (NMES), see BCBSAZ Medical Coverage Guideline #O365, *“Neuromuscular Electrical Stimulation”*.

For transcutaneous electrical nerve stimulation (TENS) for treatment of wounds, see BCBSAZ Medical Coverage Guideline #O671, *“Electrostimulation and Electromagnetic Therapy for the Treatment of Wounds”*.

For HVGS for treatment of wounds, see BCBSAZ Medical Coverage Guideline #O671, *“Electrostimulation and Electromagnetic Therapy for the Treatment of Wounds”*.

- HVGS is considered **medically necessary** for **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.
- HVGS for all other indications not previously listed or if above criteria not met is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. 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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Criteria: (cont.)

- Accelerated Recovery Performance ARPwave therapy is considered **experimental or investigational** based upon insufficient scientific evidence to permit conclusions concerning the effect on health outcomes.
- Form-fitting conductive garment is considered comfort and convenience and, therefore, a **benefit plan exclusion** and **not eligible for coverage**.
- 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** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.
- Sympathetic Therapy is considered **experimental or investigational** based upon insufficient scientific evidence to permit conclusions concerning the effect on health outcomes.
- Transcutaneous Electrical Modulation Pain Reprocessing (TEMPR) for all indications is considered **experimental or investigational** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

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Resources:

Literature reviewed 01/30/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

1. 1.04.03 BCBS Association Medical Policy Reference Manual. Sympathetic Therapy for the Treatment of Pain. Re-issue date 09/10/09, issue date 02/15/2002.
2. 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.
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.
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.
5. 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.
6. 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.
7. 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.
8. 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):2175-2177.
9. 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.
10. 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):2807-2814.



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Resources: (cont.)

11. 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.
12. 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):301-304.
13. Nelson, Hayes, Currier. *Clinical Electrotherapy*, 3rd edition. 1999.
14. NewCare Products. Micro Current Therapy™ Product Information. 2000, accessed 05/12/2004.
15. 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.
16. 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):E103-109.
17. 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.
18. 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.
19. 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):233-236.
20. UpToDate.com. Prevention and treatment of chemotherapy-induced peripheral neuropathy. 07/15/2016.
21. UpToDate.com. Psychological, rehabilitative, and integrative therapies for cancer pain. 10/19/2016.
22. Warner NS, Watson JC, Bendel MA, Moeschler SM. Refractory Pain Management in Amyloid-Associated Peripheral Neuropathy. *Regional anesthesia and pain medicine*. Jan 17 2018.



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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. 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 nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíłkídkgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíłkídkgo beehaz'áanii hółq díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ílínígóó. Ata' halne'ígíí kojí' bich'í' hodíłnih 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.



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Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:

اگر شما، یا کسی که شما به او کمک میکنید، سوال در مورد Blue Cross Blue Shield of Arizona، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 [تماس حاصل نمایید].

Assyrian:

Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoc i informacije na Vasem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือคนที่คุณกำลังช่วยเหลือถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถขอความช่วยเหลือและข้อมูลในภาษา ของคุณได้โดยไม่มีค่าใช้จ่าย โปรดขอมล โทร 877-475-4799