BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 02/05/13**
SECTION: MEDICINE	**LAST REVIEW DATE: 10/16/18**
	LAST CRITERIA REVISION DATE: 09/01/16
	ARCHIVE DATE:

ELECTROSTIMULATION AND ELECTROMAGNETIC THERAPY FOR THE TREATMENT OF WOUNDS

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.

ELECTROSTIMULATION AND ELECTROMAGNETIC THERAPY FOR THE TREATMENT OF WOUNDS (cont.)

Description:

Electrical Stimulation:
Electrical stimulation refers to the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. The types of electrical stimulation and devices can be categorized into 4 groups based on the type of current:

1. Alternating current (AC)
2. High voltage pulsed current (HVPC); also known as high voltage galvanic stimulation (HVGS)
3. Low-intensity direct current (LIDC)
4. Transcutaneous electrical nerve stimulation (TENS)

Electromagnetic and Shortwave Diathermy Devices:
Pulsed electromagnetic devices use radiofrequency signals for therapeutic heating of tissue. The signals are delivered through coils that do not directly contact the skin.

Shortwave diathermy or radiofrequency stimulation devices are another type of electromagnetic therapy. These devices use radiofrequency electromagnetic fields for therapeutic heating of tissue. Several shortwave diathermy devices have been FDA-approved for treatment of postoperative pain and edema in superficial tissue. These include Provant® Therapy System and SofPulse®. Shortwave diathermy or radiofrequency electromagnetic devices have been investigated as a technique to promote wound healing.

There are no electromagnetic therapy devices or shortwave diathermy devices approved by the FDA for the treatment of wound healing.

ELECTROSTIMULATION AND ELECTROMAGNETIC THERAPY FOR THE TREATMENT OF WOUNDS (cont.)

Description: (cont.)

Wound Definitions[1]:

Stage I:
Nonblanchable erythema of intact skin.

Stage II:
Partial thickness skin loss involving epidermis and/or dermis.

Stage III:
Full thickness skin loss involving damage or necrosis of subcutaneous tissues that may extend down to, but not through, underlying fascia.

Stage IV:
Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone or supporting structures.

Chronic:
A wound or condition present for at least 30 days despite standard medical and surgical management.

1 Agency for Health Care Policy and Research (AHCPR)

ELECTROSTIMULATION AND ELECTROMAGNETIC THERAPY FOR THE TREATMENT OF WOUNDS (cont.)

Criteria:

For electrical stimulation for non-wound treatment, see BCBSAZ Medical Coverage Guideline #O243, *"Electrical Stimulation"*.

Electrical Stimulation:

- Electrical stimulation for treatment of wounds 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.

  Electrical stimulation devices include, *but are not limited to*:

  - Alternating current (AC)
  - High voltage pulsed current (HVPC); also known as high voltage galvanic stimulation (HVGS)
  - Low-intensity direct current (LIDC)
  - Transcutaneous electrical nerve stimulation (TENS)

ELECTROSTIMULATION AND ELECTROMAGNETIC THERAPY FOR THE TREATMENT OF WOUNDS (cont.)

Criteria: (cont.)

Electromagnetic and Shortwave Diathermy:

- Electromagnetic therapy and shortwave diathermy for the treatment of wounds is considered ***experimental or investigational*** based upon:.

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

  Wound types include, *but are not limited to*:

  - Chronic vascular ulcers
  - Decubitus ulcers with or without bone involvement
  - Diabetic ulcers
  - Pressure ulcers
  - Venous ulcers
  - Draining wounds
  - Partial **or** full thickness wounds
  - Tunneled, undermined wounds
  - Surgical wounds (i.e., donor sites/grafts, post-Mohs' surgery, post-laser surgery, podiatric, wound dehiscence)
  - Trauma wounds (i.e., abrasions, lacerations, second-degree burns, skin tears)

Resources:

Literature reviewed 10/16/18. 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.

Resources prior to 02/05/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 2.01.57 BCBS Association Medical Policy Reference Manual. Electrostimulation and Electromagnetic Therapy for Treating Wounds. Re-issue date 01/11/2018, issue date 07/17/2003.

ELECTROSTIMULATION AND ELECTROMAGNETIC THERAPY FOR THE TREATMENT OF WOUNDS (cont.)

Resources: (cont.)

FDA Summary Statements for shortwave diathermy. Device names include, *but are not limited to*:

Provant® Therapy System
SofPulse®

- FDA-approved indication: Adjunctive use in the palliative treatment of postoperative edema and pain in superficial soft tissue.

ELECTROSTIMULATION AND ELECTROMAGNETIC THERAPY FOR THE TREATMENT OF WOUNDS (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. 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 nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hólǫ díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh ílínígóó. Ata' halne'ígíí kojį' bich'į' 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 تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة .للتحدث مع مترجم اتصل ب 877-475-4799.

ELECTROSTIMULATION AND ELECTROMAGNETIC THERAPY FOR THE TREATMENT OF WOUNDS (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulangan, 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:
ܐ ܫܟܚ، ܡ ܣ ܩܙܝܩܐ ܕܡܝܢܐ ܒܗ، ܫܟܚ ܫܟܚܗ ܚܒܪܐ ܕܐ Blue Cross Blue Shield of Arizona، ܫܟܚ ܫܟܚܗ ܚܒܪܐ ܕܐ ܕܡܝܢܐ ܒܗ، ܫܟܚ ܫܟܚ
ܐ ܫܟܚ، ܡ ܣ ܩܙܝܩܐ ܕܡܝܢܐ ܒܗ، ܫܟܚ ܫܟܚܗ ܚܒܪܐ ܕܐ ܕܡܝܢܐ ܒܗ، ܫܟܚ ܫܟܚ
877-475-4799 ،ܐ ܫܟܚ، ܡ ܣ ܩܙܝܩܐ ܕܡܝܢܐ ܒܗ، ܫܟܚ ܫܟܚܗ ܚܒܪܐ ܕܐ ܕܡܝܢܐ ܒܗ، ܫܟܚ ܫܟܚ

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: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799