**Medical Coverage Policy** | Electrical Stimulation and Electromagnetic Therapy for Wound Treatment



**EFFECTIVE DATE:** 10|01|2005 **POLICY LAST UPDATED:** 09|15|2015

### **OVERVIEW**

Electrical stimulation or electrostimulation (ES) refers to the application of electrical current through electrodes placed directly on the skin. Electromagnetic therapy involves the application of electromagnetic fields rather than direct electrical current. Both are proposed as treatments for wounds, generally chronic wounds.

### **MEDICAL CRITERIA**

Not applicable

## **PRIOR AUTHORIZATION**

Not applicable

## **POLICY STATEMENT**

### **BlueCHiP** for Medicare

Electrical stimulation and electromagnetic therapy for the treatment of chronic wounds is covered when used for the indications listed in the background.

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates scientific evidence with local expert opinion, and consideration of governmental regulations from the Centers for Medicare and Medicaid Services (CMS), such as national coverage determinations or local coverage determinations. and the US Congress. BCBSRI policy is based upon peer-reviewed, scientifically controlled studies in the literature which demonstrate the superior health outcome of a service or treatment. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. BCBSRI and Medicare policies may differ; however, our BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers. (In some, but not all instances, BCBSRI offers more benefits than does Medicare).

## **Commercial Products**

Electrical stimulation and electromagnetic therapy for the treatment of chronic wounds is considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

## COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically benefits/coverage.

### BACKGROUND

The normal wound healing process involves inflammatory, proliferative, and remodeling phases. When the healing process fails to progress properly and the wound persists for longer than 1 month, it may be described as a chronic wound. The types of chronic wounds most frequently addressed in studies of electrical stimulation for wound healing are: 1) pressure ulcers, 2) venous ulcers, 3) arterial ulcers, and 4) diabetic ulcers. Conventional or standard therapy for chronic wounds involves local wound care, as well as systemic measures including debridement of necrotic tissues, wound cleansing, and dressing that promotes a moist wound

environment, antibiotics to control infection, and optimizing nutritional supplementation. Not bearing weight is another important component of wound management.

Since the 1950s, investigators have used electrical stimulation as a technique to promote wound healing, based on the theory that electrical stimulation may:

- Increase adenosine 5'-triphosphate (ATP) concentration in the skin
- Increase DNA synthesis
- Attract epithelial cells and fibroblasts to wound sites
- Accelerate the recovery of damaged neural tissue
- Reduce edema
- Increase blood flow
- Inhibit pathogenesis

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) low-intensity direct current (LIDC), 2) high-voltage pulsed current (HVPC), 3) alternating current (AC), and 4) transcutaneous electrical nerve stimulation (TENS). Electromagnetic therapy is a related but distinct form of treatment that involves the application of electromagnetic fields rather than direct electrical current.

Currently, no electrical stimulation or electromagnetic therapy devices have received approval from the U.S. Food and Drug Administration (FDA), specifically for the treatment of wound healing. A number of devices have been cleared for marketing for other indications. Use of these devices for wound healing is an off-label indication.

There is insufficient evidence from well-designed randomized controlled trials (RCTs) that electrostimulation or electromagnetic stimulation improves health outcomes for wound care patients beyond that provided by standard treatment. Some small RCTs on electrostimulation have reported improvements in some intermediate outcomes, such as decrease in wound size and/or the velocity of wound healing. However, these studies have not demonstrated consistent improvements on the more important clinical outcomes of complete healing and the time to complete healing. For electromagnetic therapy, there is a lack of high-quality RCTs. Therefore, these treatments are considered not medically necessary for the treatment of wounds as there is no proven efficacy.

# **BlueCHiP** for Medicare

# A. Nationally Covered Indications

The use of ES and electromagnetic therapy for the treatment of wounds are considered adjunctive therapies, and will only be covered for chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers. Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence. ES or electromagnetic therapy will be covered only after appropriate standard wound therapy has been tried for at least 30 days and there are no measurable signs of improved healing. This 30-day period may begin while the wound is acute.

Standard wound care includes: optimization of nutritional status, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, and necessary treatment to resolve any infection that may be present. Standard wound care based on the specific type of wound includes: frequent repositioning of a patient with pressure ulcers (usually every 2 hours), offloading of pressure and good glucose control for diabetic ulcers, establishment of adequate circulation for arterial ulcers, and the use of a compression system for patients with venous ulcers.

Measurable signs of improved healing include: a decrease in wound size (either surface area or volume), decrease in amount of exudates, and decrease in amount of necrotic tissue. ES or electromagnetic therapy must be discontinued when the wound demonstrates 100% epitheliliazed wound bed.

ES and electromagnetic therapy services can only be covered when performed by a physician, physical therapist, or incident to a physician service. Evaluation of the wound is an integral part of wound therapy. When a physician, physical therapist, or a clinician incident to a physician, performs ES or electromagnetic therapy, the practitioner must evaluate the wound and contact the treating physician if the wound worsens. If ES or electromagnetic therapy is being used, wounds must be evaluated at least monthly by the treating physician.

# B. Nationally Noncovered Indications

1. ES and electromagnetic therapy will not be covered as an initial treatment modality.

2. Continued treatment with ES or electromagnetic therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

3. Unsupervised use of ES or electromagnetic therapy for wound therapy will not be covered, as this use has not been found to be medically reasonable and necessary.

**\*Note:** Medicare's definition of unattended means the procedure must be supervised by a health care provider but the provider does not have to be in constant attendance.

# CODING

The following codes are covered for BlueCHiP for Medicare and not medically necessary for all other BCBSRI products:

**G0281** Electrical stimulation (unattended\*) to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care

**G0329** Electromagnetic therapy to one or more areas for chronic stage III and stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care

The following codes are considered not medically necessary for all BCBSRI products:

**G0282** Electrical stimulation (unattended), to one or more areas, for wound care other than described in G0281.

**G0295** Electromagnetic therapy, to one or more areas, for wound care other than described in G0329 or for other uses.

The following codes are not separately reimbursed for all BCBSRI products:

**E0761** Non-thermal pulsed high frequency radiowaves, high peek power electromagnetic energy treatment device.

**E0769** Electrical stimulation or electromagnetic wound treatment device, not otherwise classified.

# **RELATED POLICIES**

None

# PUBLISHED

Provider Update, November 2015 Provider Update, January 2014 Provider Update, February 2013 Provider Update, March 2012 Provider Update, December 2010 Provider Update, December 2009 Provider Update, October 2008 Policy Update, March 2008 Policy Update, March 2007 Policy Update, February 2006 Policy Update, February 2001 Policy Update, August 2001

## REFERENCES

1. Medicare Technology Assessments for Electrostimulation for Wounds (CAG-00068N). http://www.cms.gov/medicare-coverage-database/details/technology-assessmentsdetails.aspx?TAId=13&NCAId=27&NcaName=Electrostimulation+for+Wounds&IsPopup=y&bc=AAAA AAAACAAAAA%3d%3d&. Accessed July, 2014.

2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Electrical stimulation or electromagnetic therapy as adjunctive treatments for chronic skin wounds. TEC Assessments. 2005;Volume 20, Tab 2. PMID

3. Barnes R, Shahin Y, Gohil R, et al. Electrical stimulation vs. standard care for chronic ulcer healing: a systematic review and meta-analysis of randomised controlled trials. Eur J Clin Invest. Apr 2014;44(4):429-440. PMID 24456185

4. Kawasaki L, Mushahwar VK, Ho C, et al. The mechanisms and evidence of efficacy of electrical stimulation for healing of pressure ulcer: a systematic review. Wound Repair Regen. Mar-Apr 2014;22(2):161-173. PMID 24372691

5. Franek A, Kostur R, Polak A, et al. Using high-voltage electrical stimulation in the treatment of recalcitrant pressure ulcers: results of a randomized, controlled clinical study. Ostomy Wound Manage. Mar 2012;58(3):30-44. PMID 22391955

6. Houghton PE, Campbell KE, Fraser CH, et al. Electrical stimulation therapy increases rate of healing of pressure ulcers in community-dwelling people with spinal cord injury. Arch Phys Med Rehabil. 2010;91(5):669-678. PMID

7. Liu LQ, Moody J, Traynor M, et al. A systematic review of electrical stimulation for pressure ulcer prevention and treatment in people with spinal cord injuries. J Spinal Cord Med. Jun 26 2014. PMID 24969965

8. Adunsky A, Ohry A, Ddct G. Decubitus direct current treatment (DDCT) of pressure ulcers: results of a randomized double-blinded placebo controlled study. Arch Gerontol Geriatr. 2005;41(3):261-269. PMID

9. Aziz Z, Flemming K. Electromagnetic therapy for treating pressure ulcers. Cochrane Database Syst Rev. 2012;12:CD002930. PMID 23235593

#### ----- CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.