

# Protocol

## Electrostimulation and Electromagnetic Therapy for Treating Wounds

(20157)

|                         |    |  |                                |
|-------------------------|----|--|--------------------------------|
| <b>Medical Benefit</b>  |    | <b>Effective Date:</b> 04/01/14  | <b>Next Review Date:</b> 03/21 |
| <b>Preauthorization</b> | No | <b>Review Dates:</b> 07/07, 07/08, 05/09, 03/10, 01/11, 01/12, 01/13, 01/14, 11/14, 11/15, 11/16, 03/17, 03/18, 03/19, 03/20 |                                |

### **Preauthorization is not required.**

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

| Populations  | Interventions  | Comparators  | Outcomes   |
|--|--|--|--|
| Individuals: <ul style="list-style-type: none"><li>• With any wound type (acute or nonhealing)</li></ul> | Interventions of interest are: <ul style="list-style-type: none"><li>• Electrostimulation</li></ul>      | Comparators of interest are: <ul style="list-style-type: none"><li>• Standard wound care</li></ul> | Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Change in disease status</li><li>• Morbid events</li><li>• Quality of Life</li><li>• Treatment-related morbidity</li></ul> |
| Individuals: <ul style="list-style-type: none"><li>• With any wound type (acute or nonhealing)</li></ul> | Interventions of interest are: <ul style="list-style-type: none"><li>• Electromagnetic therapy</li></ul> | Comparators of interest are: <ul style="list-style-type: none"><li>• Standard wound care</li></ul> | Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Change in disease status</li><li>• Morbid events</li><li>• Quality of Life</li><li>• Treatment-related morbidity</li></ul> |

### **DESCRIPTION**

Electrostimulation (electrical stimulation) 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.

### **SUMMARY OF EVIDENCE**

For individuals who have any wound type (acute or nonhealing) who receive electrostimulation, the evidence includes systematic reviews, a meta-analysis, and randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in health status, morbid events, quality of life, and treatment-related morbidity. Systematic reviews of RCTs on electrical stimulation have reported improvements in some outcomes, mainly intermediate outcomes such as a decrease in wound size and/or the velocity of wound healing. There are few analyses of the more important clinical outcomes of complete healing and the time to complete healing, and many of the trials are relatively low quality. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have any wound type (acute or nonhealing) who receive electromagnetic therapy, the evidence includes two systematic reviews of RCTs (one on pressure ulcers and the other on leg ulcers) and an RCT of electromagnetic treatment following Cesarean section. Relevant outcomes are symptoms, change in health status, morbid events, quality of life, and treatment-related morbidity. The systematic reviews identified a few RCTs with small sample sizes that do not permit drawing definitive conclusions. The evidence is insufficient to determine the effects of the technology on health outcomes.

## POLICY

Electrical stimulation for the treatment of wounds, including but not limited to low-intensity direct current, high-voltage pulsed current, alternating current, and transcutaneous electrical nerve stimulation is considered **investigational**.

Electrical stimulation performed by the patient in the home setting for the treatment of wounds is considered **investigational**.

Electromagnetic therapy for the treatment of wounds is considered **investigational**.

## MEDICARE ADVANTAGE

For Medicare Advantage the use of electrical stimulation and electromagnetic therapy for the treatment of wounds are **medically necessary** adjunctive therapies for chronic<sup>1</sup> Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers only after appropriate standard wound therapy<sup>2</sup> has been tried for at least 30 days with no measurable signs of improved healing<sup>3</sup> and when performed by a physician or physical therapist.

Electrical stimulation and electromagnetic therapy is **not medically necessary** as an initial treatment modality.

Continued treatment is **not medically necessary** if measurable signs of healing<sup>3</sup> have not been demonstrated within any 30-day period of treatment.

Unsupervised use and all other use of electrical stimulation or electromagnetic therapy for wound therapy are **not medically necessary**.

<sup>1</sup>Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence. This 30-day period may begin while the wound is acute.

<sup>2</sup>The standard wound care that would be expected to be tried 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 two 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.

<sup>3</sup>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% epithelialized wound bed.

## BACKGROUND

### CHRONIC WOUNDS

The normal wound healing process involves inflammatory, proliferative, and remodeling phases. When the heal-

ing process fails to progress properly, and the wound persists for more than one 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.

#### Treatment

Conventional or standard therapy for chronic wounds involves local wound care, as well as systemic measures including débridement of necrotic tissues, wound cleansing, and dressing that promotes a moist wound environment, antibiotics to control infection, and optimizing nutritional supplementation. Avoidance of weight bearing is another important component of wound management.

#### Electrostimulation

Since the 1950s, investigators have used electrostimulation to promote wound healing, based on the theory that electrostimulation may:

- Increase adenosine 5-triphosphate 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.

Electrostimulation refers to the application of electrical current through electrodes placed directly on the skin near the wound. The types of electrostimulation and devices can be categorized into groups based on the type of current. This includes low-intensity direct current, high-voltage pulsed current, alternating current, and transcutaneous electrical nerve stimulation.

#### Electromagnetic Therapy

Electromagnetic therapy is a related but distinct form of treatment that involves the application of electromagnetic fields, rather than direct electrical current.

### REGULATORY STATUS

No electrostimulation or electromagnetic therapy devices have received approval from the U.S. Food and Drug Administration 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 off-label.

### RELATED PROTOCOLS

Negative Pressure Wound Therapy in the Outpatient Setting

Transcutaneous Electrical Nerve Simulation

---

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary

Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. 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.
2. 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
3. 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
4. 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.* May 2010;91(5):669-678. PMID 20434602
5. 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
6. Lala D, Spaulding SJ, Burke SM, et al. Electrical stimulation therapy for the treatment of pressure ulcers in individuals with spinal cord injury: a systematic review and meta-analysis. *Int Wound J.* Dec 2016;13(6):1214-1226. PMID 25869151
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.* Nov 2014;37(6):703-718. PMID 24969965
8. Thakral G, La Fontaine J, Kim P, et al. Treatment options for venous leg ulcers: effectiveness of vascular surgery, bioengineered tissue, and electrical stimulation. *Adv Skin Wound Care.* Apr 2015;28(4):164-172. PMID 25775200
9. Khouri C, Kotzki S, Roustit M, et al. Hierarchical evaluation of electrical stimulation protocols for chronic wound healing: An effect size meta-analysis. *Wound Repair Regen.* Oct 20 2017. PMID 29052946
10. Polak A, Kloth LC, Blaszczak E, et al. The Efficacy of Pressure Ulcer Treatment With Cathodal and Cathodal-Anodal High-Voltage Monophasic Pulsed Current: A Prospective, Randomized, Controlled Clinical Trial. *Phys Ther.* Aug 1 2017;97(8):777-789. PMID 28789467
11. Aziz Z, Flemming K. Electromagnetic therapy for treating pressure ulcers. *Cochrane Database Syst Rev.* Dec 12 2012;12:CD002930. PMID 23235593
12. Aziz Z, Cullum N. Electromagnetic therapy for treating venous leg ulcers. *Cochrane Database Syst Rev.* Jul 2 2015;7:CD002933. PMID 26134172

13. Khooshideh M, Latifi Rostami SS, Sheikh M, et al. Pulsed electromagnetic fields for postsurgical pain management in women undergoing cesarean section: a randomized, double-blind, placebo-controlled trial. *Clin J Pain*. Feb 2017;33(2):142-147. PMID 28060214
14. Qaseem A, Humphrey LL, Forciea MA, et al. Treatment of pressure ulcers: a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. Mar 3 2015;162(5):370-379. PMID 25732279
15. Bolton LL, Girolami S, Corbett L, et al. The Association for the Advancement of Wound Care (AAWC) venous and pressure ulcer guidelines. *Ostomy Wound Manage*. Nov 2014;60(11):24-66. PMID 25380098
16. Association for the Advancement of Wound Care (AAWC). Association for the Advancement of Wound Care guideline of pressure ulcer guidelines. Malvern, PA: AAWC; 2010.
17. Wound Ostomy and Continence Nurses Society (WOCN). Guideline for prevention and management of pressure ulcers (injuries). 2016; <https://www.guideline.gov/summaries/summary/50473>. Accessed January 3, 2018.
18. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds (270.1). 2004; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=131&ver=3>. Accessed January 3, 2018.
19. National Coverage Determination (NCD) for Electrical Stimulation (ES) and ELECTROMAGNETIC THERAPY for the Treatment of WOUNDS (270.1), Implementation Date 7/6/2004.
20. National Government Services, Inc. (Primary Geographic Jurisdiction 06 & K - Illinois, Minnesota, Wisconsin, Connecticut, New York - Entire State, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont) Local Coverage Determination (LCD): Outpatient Physical and Occupational THERAPY Services (L33631), Revision Effective Date for services performed on or after 01/01/2020.