Protocol

Electrostimulation and Electromagnetic Therapy for Treating Wounds

(20157)

Medical Benefit		**Effective Date**: 04/01/14	**Next Review Date**: 01/15
Preauthorization	No	**Review Dates**: 07/07, 07/08, 05/09, 03/10, 01/11, 01/12, 01/13, 01/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required but recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.*** *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.*

Description

Electrical stimulation refers to the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. Electromagnetic therapy involves the application of electromagnetic fields rather than direct electrical current. Both are proposed as treatments for chronic wounds.

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 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. 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. Non-weight bearing 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 four 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.

Regulatory Status

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.

Related Protocols

Transcutaneous Electrical Nerve Stimulation (TENS)

Negative Pressure Wound Therapy in the Outpatient Setting

Policy (Formerly Corporate Medical Guideline)

Electrical stimulation for the treatment of wounds, including but not limited to low-intensity direct current (LIDC), high-voltage pulsed current (HVPC), alternating current (AC), and transcutaneous electrical nerve stimulation (TENS) 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[1] Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers only after appropriate standard wound therapy[2] has been tried for at least 30 days with no measurable signs of improved healing[3] 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[3] 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**.

[1]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.

[2]The standard wound care that would 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.

[3]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.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment 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. Medicare Technology Assessments for Electrostimulation for Wounds (CAG-00068N). Available online at: http://www.cms.gov/medicare-coverage-database/details/technology-assessments-details.aspx?TAId=13&NCAId=27&NcaName=Electrostimulation+for+Wounds&IsPopup=y&bc=AAAAAAAACAAAAA%3d%3d&. Last accessed September, 2013.
3. Game FL, Hinchliffe RJ, Apelqvist J et al. A systematic review of interventions to enhance the healing of chronic ulcers of the foot in diabetes. Diabetes Metab Res Rev 2012; 28 Suppl 1:119-41.
4. Aziz Z, Flemming K. Electromagnetic therapy for treating pressure ulcers. Cochrane Database Syst Rev 2012; 12:CD002930.
5. Aziz Z, Cullum N, Flemming K. Electromagnetic therapy for treating venous leg ulcers. Cochrane Database Syst Rev 2013; 2:CD002933.
6. 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):261-9.
7. 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):669-78.
8. 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 2012; 58(3):30-44.
9. Gupta A, Taly AB, Srivastava A et al. Efficacy of pulsed electromagnetic field therapy in healing of pressure ulcers: a randomized control trial. Neurol India 2009; 57(5):622-26.
10. Association for the Advancement of Wound Care (AAWC). Association for the Advancement of Wound Care guideline of pressure ulcer guidelines. Available online at: www.guideline.gov. Last accessed September, 2013.
11. CMS Manual System. Pub. 100-43 Medicare National Coverage Determinations. 2004. Available online at: www.cms.hhs.gov. Last accessed September, 2013.