

Protocol

Electrostimulation and Electromagnetic Therapy for Treating Wounds

(20157)

Medical Benefit		Effective Date: 04/01/14	Next Review Date: 03/18
Preauthorization	No	Review Dates: 07/07, 07/08, 05/09, 03/10, 01/11, 01/12, 01/13, 01/14, 11/14, 11/15, 11/16, 03/17	

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

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

The evidence for electrostimulation for treating individuals who have any wound type (acute or nonhealing) includes systematic reviews, randomized controlled trials (RCTs), and observational studies. 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 decrease in wound size and/or the velocity of wound healing. There are few analyses on the more important clinical outcomes of complete healing and the time to complete healing, and many of the trials are of relatively low quality. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for electromagnetic stimulation for treating individual who have any wound type (acute or non-healing) includes two systematic reviews of RCTs, one on pressure ulcers and the other on leg ulcers. 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 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 chronic¹ Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers only after appropriate standard wound therapy² has been tried for at least 30 days with no measurable signs of improved healing³ 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 healing³ 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**.

¹Chronic 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.

²The 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.

³Measurable 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

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 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.

Since the 1950s, investigators have used electrical stimulation to promote wound healing, based on the theory that electrical stimulation 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

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 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 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 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 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.

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13. Wound O, and Continence Nurses Society (WOCN). Guideline for prevention and management of pressure ulcers. 2015. Available at: <http://www.guideline.gov/content.aspx?id=23868>. Accessed December 6.
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15. National Government Services, Inc. Local Coverage Determination (LCD): Outpatient Physical and Occupational THERAPY Services (L33631), Revision Effective Date for services performed on or after 01/01/2017.