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Medical Policy Manual

Topic: Electrostimulation and Electromagnetic Therapy for the Treatment of Wounds

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Section: DME

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

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:

- Low intensity direct current (LIDC)
- High voltage pulsed current (HVPC)
- Alternating current (AC)
- 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.

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 or electromagnetic therapy for wound healing are:

- Pressure ulcers
- Venous ulcers
- Arterial ulcers
- Diabetic ulcers

Conventional or standard therapy for chronic wounds involves local wound care as well as systemic measures including debridement of necrotic tissue, wound cleansing, and dressing that promote a moist wound environment, antibiotics to control infection and optimizing nutritional supplementation. Wound care may be conducted by medical professionals in the clinical or home setting, or by patients themselves, typically in the home setting.

Regulatory Status

At the present time there are no electrical stimulation devices that have received U.S. Food and Drug Administration (FDA) approval 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.

MEDICAL POLICY CRITERIA

Electrical stimulation and electromagnetic therapy for the treatment of wounds is considered **investigational**. All electrical stimulation devices are included in the category, including but not limited to, low-intensity direct current (LIDC), high-voltage pulsed current (HVPC), alternating current (AC), and transcutaneous electrical nerve stimulation (TENS)*.

***Note:** Electrical stimulation as a treatment of pain and other musculoskeletal conditions are considered in separate plan Medical Policies. See Cross References.

SCIENTIFIC EVIDENCE

The principal outcomes associated with treatment of wounds, particularly chronic wounds, are complete wound closure, improvement in the rate or quality of healing (such as the minimization of scarring), treatment of infection, and patient-centered outcomes such as improvements in function or mobility, and minimization of pain.[1] Outcomes relating to the use of a device delivering electrical stimulation or electromagnetic therapy for the treatment of wounds are best understood when comparing use of either type of device to a sham device among patients with similar wound type (i.e., burn or chronic diabetic ulcer), who are receiving standardized wound care regimens. Therefore, data from adequately powered, blinded, randomized sham-controlled trials are required to control for bias and determine whether any treatment effect from electrical stimulation or electromagnetic therapy devices provides a significant advantage over standard wound care.

Literature Appraisal

Technology Assessments

In February 2005, a BlueCross BlueShield Association Technology Evaluation Center (TEC) Assessment on electrostimulation and electromagnetic therapy for the treatment of chronic wounds was conducted.[2] The following summarizes the conclusions of the TEC Assessment:

- The most clinically important outcome in evaluating treatments for wound healing is the percent of patients that heal completely following a course of treatment. Time to complete healing is another important, objective outcome measure. Secondary outcomes that have some clinical relevance are decrease in the size of a wound, pain associated with a wound, and facilitation of surgical closure. Adverse outcomes with electrical stimulation and electromagnetic therapy are expected to be minimal but may include discomfort and infection associated with the device.

- The evidence is not sufficient to permit conclusions on the efficacy of electrical stimulation and electromagnetic therapy as adjunctive treatments for wound healing. For studies of wound healing, high-quality randomized, controlled trials (RCTs) are essential to determining the efficacy of an intervention independent of the many confounding factors and the variable natural history of the disorder. The body of evidence for electrical stimulation and electromagnetic therapy consisted of numerous small, relatively poor-quality RCTs (N=10 for electrical stimulation; N=5 for electromagnetic therapy) that compared active treatment with a placebo sham device.

- Although results suggest that electrical stimulation and electromagnetic therapy may promote wound healing or some aspect of wound healing, considerable uncertainty remains as to whether these modalities lead to clinically significant health outcome benefits, given the relatively poor quality of the available evidence. Larger RCTs are needed that focus on one type of wound, that demonstrate baseline comparability on important confounders, and that report the outcome of complete healing.

Systematic Reviews

Subsequent to the TEC Assessment, several systematic reviews on treatments for wounds have been published that address electrostimulation and electromagnetic therapy.

- In 2012, Game and colleagues reviewed studies on interventions to enhance healing of diabetic foot ulcers and stated that they did not find sufficient evidence that electrical stimulation was clinically effective for treating foot ulcers.[3]

- Aziz and colleagues published two Cochrane reviews which evaluated electromagnetic stimulation for treating wounds; one addressed treatment of pressure ulcers and the other addressed leg ulcers.[4-7] Each review identified few RCTs (2 and 3 studies, respectively) with small sample sizes. Consequently, the investigators were not able to conduct robust pooled analyses of study findings. Both reviews concluded that there was insufficient evidence that electromagnetic therapy is effective for treating chronic wounds.

- In 2001, Ravaghi and colleagues conducted a Cochrane review on electromagnetic therapy treatment for leg ulcers.[8] This review was later updated in 2011, and authors' concluded that

further research was needed and that there was limited evidence (3 randomized trials, one showing no difference between groups) to conclude any benefit of electromagnetic therapy.

- In another Cochrane database review, by the same group, electromagnetic stimulation was evaluated as a treatment for pressure ulcers.[9] Once again, limited evidence from randomized trials (2 trials with a total of 60 patients) was available and of the two studies identified, no differences were found between healing rates of pressure ulcers compared to the control group.

- In 2013, the Agency for Healthcare Research and Quality (AHRQ) published a comparative effectiveness review to evaluate the optimal treatment strategy for pressure ulcers.[10] Although the group considers complete wound healing to be the primary outcome of interest, wound improvement was also considered, as "it represents a necessary intermediate step toward the principal outcome of complete wound healing…(and) the likelihood of complete wound healing is lower for larger or higher staged ulcers." A moderate and low recommendation for acceleration of healing and wound improvement was given to electrical stimulation and electromagnetic therapy, respectively. A moderate strength of evidence was defined as, "moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate." Low was defined as, "low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate." However, the agency did note that while electric stimulation and electromagnetic therapy show a tendency toward wound improvement, neither demonstrated consistent effectiveness in complete wound healing.

Randomized Controlled Trials

Subsequent to the systematic reviews previously addressed, several randomized controlled trials (RCTs) have been published which address electric stimulation as treatment for wounds.

- Ud-Dine and colleagues conducted a small randomized study on electrical stimulation treatment for acute cutaneous wounds.[11] Twenty patients, with a mean age of 23 years, underwent temporal punch biopsy in both arms at different time periods in the study. Patients were then randomized to receive localized electrical stimulation in either the right or left arm. An improvement in melanin and hemoglobin levels was observed in the treatment group over the observation group. However, this study is limited by its small sample size and a lack of data regarding wound healing.

- Franek and colleagues investigated the effects of high-voltage electrical stimulation (HVES) on nonhealing, lower-extremity, stage II and stage III pressure ulcers. All patients received standard supportive care and topical treatments covered with wet-to-moist dressings. Patients in the treatment group also received HVES (100 V; 100 μs; 100 Hz) continuously for 50 minutes a day, 5 times/week. Fifty-seven patients were recruited over a 4-year period of which 50 patients (88%) completed treatment. Although improvement was observed in both groups, wound area, linear measurement, wound volume, and granulation tissue changes were statistically significantly greater in the treatment than in the control group. At the end of the 6 week follow-up, surface area change was 88.8% (SD 14) in the treatment group and 44.4% (SD 63.1) in the control group ($p=0.00003$). Wound healing was not reported due to the short 6 week follow-up period. Limitations of this study included the small sample size and limited follow-up time which preclude conclusions about the effectiveness of HVES as a treatment for lower-extremity

pressure ulcers. In addition, authors noted that further research was needed to determine the optimal duration of treatment and type of HVES stimulation.

- In 2005, Adunsky and colleagues published a randomized, double-blind, placebo-controlled trial to determine the benefits of adding direct current electrostimulation to conservative wound care for stage-III degree pressure sores of 30 days' to 24 months' duration.[12] This multicenter trial of 63 patients found no significant differences in complete wound closure or time to complete wound closure between the treatment groups after 8 consecutive weeks of electrostimulation. Nor were there any significant differences between groups after an additional follow-up of 12 weeks. While the authors reported an increase in absolute wound area reduction and speed of wound healing up until the 45th day of treatment in the electrostimulation group, this was not statistically significant and did not result in a greater rate of complete wound closure.

- Houghton and colleagues reported on a small (n=34) randomized controlled trial comparing pressure wound healing (as measured by reduction in wound size at 3 months) with and without use of electrical stimulation on a group of patients with spinal cord injury in a community-based home setting.[13] Following 3 months of treatment (where patients, family members, and/or home care nurses were responsible for delivery of electrical stimulation with the Micro-Z™ device [Prizm Medical, Inc.]), the group receiving electrical stimulation in addition to standard wound treatment reported a significantly greater decrease in wound surface area compared with the treatment group receiving standard wound treatment alone (mean decrease: 70% vs. 61%, respectively, p=.048). (Of note, the Micro-Z device has clearance from the FDA for use in pain relief; wound treatment is an off-label use of this device.) Although the difference in wound size between treatment groups (9%) attained statistical significance, the clinical significance of such a difference was not reported. Secondary outcomes included difference in number of patients who had attained complete wound closure at 6 months; no significant difference was found between the treatment groups (6 patients in the electrical stimulation group versus 5 in the standard wound care group attained complete wound closure). These results are limited by lack of comparison with a sham treatment group. A comparable sham control group would help control for placebo effects as well as for the variable natural history of wound healing. Additionally, study of intermediate health outcomes (i.e., comparisons in proportion of wound healing) does not permit conclusions about improvement in short- or long-term primary health outcomes (such as complete wound closure). Although no statistical difference was found in complete wound closure between the treatment groups, the study may not have been sufficiently large to detect such a difference. Studies with larger sample sizes and longer duration may be required to evaluate whether treatment difference exists.

Clinical Practice Guidelines

Association for the Advancement of Wound Care (AAWC)

In 2010, the AAWC published a guideline on care of pressure ulcers.[14] Electrical stimulation was included as a potential second-line intervention if first-line treatments did not result in wound healing. However, the group noted that electrical stimulation was not compared in a randomized controlled trial to standard dressing treatment for wounds. The guideline did not address electromagnetic therapy.

Summary

At present, there is insufficient evidence from large well-designed randomized controlled trials (RCTs) to determine whether electrical stimulation or electromagnetic therapy improves wound healing compared with conventional wound care techniques. Current studies have not demonstrated consistent improvements in the more important clinical outcomes of complete healing. Nor have studies demonstrated that these therapies are beneficial over the standard of care for the treatment of wounds. Therefore, the use of either electrostimulation or electromagnetic therapy is considered investigational for the treatment of wounds.

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CROSS REFERENCES

Electrical Stimulation Devices Index, DME, Policy No. 83

Interferential Current Stimulation, DME, Policy No. 83.07

Electrical Stimulation and Electromagnetic Therapy for the Treatment of Arthritis, DME, Policy No. 83.10

Non-Contact Ultrasound Treatments for Wounds, Medicine, Policy No. 131

CODES	NUMBER	DESCRIPTION
CPT	None	
HCPCS	E0761	Non-thermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device.
	E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
	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.
	G0282	Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281
	G0295	Electromagnetic stimulation, to one or more areas, for wound care other than described in G0329 or for other uses
	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