Electrostimulation and Electromagnetic Therapy for the Treatment of Wounds

Effective: July 1, 2017

Next Review: June 2018
Last Review: June 2017

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.

MEDICAL POLICY CRITERIA

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

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: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Electrical Stimulation Devices Index, DME, Policy No. 83
2. Interferential Current Stimulation, DME, Policy No. 83.07
BACKGROUND

The types of electrical stimulation and devices can be categorized into four 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 one 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 ulcers, and include but are not limited to, pressure, venous, arterial, and diabetic.

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.

EVIDENCE SUMMARY

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.

SYSTEMATIC REVIEWS
Aziz and Bell (2015) published a SR update that assessed the effects electromagnetic therapy (EMT) versus sham EMT on the healing of pressure ulcers. No new RCTs were identified and of the two included, there was no significant differences in complete wound healing between the groups. One RCT identified a significant reduction in wound surface area with EMT treatment. The authors concluded there was no strong evidence to support EMT for the treatment of pressure ulcers and the one study that showed EMT effective in the treatment of pressure ulcers was small. Both RCTs had methodological limitations.

Aziz and Cullum (2015) published results from a systematic review (SR) that assessed the effects of electromagnetic therapy (EMT) on the healing of venous leg ulcers. Three randomized controlled trials were included were included in the review comprising 94 people. All trials included in the review compared the use of EMT with sham-EMT; however, due to heterogeneity a meta-analysis could not be completed. Two of the trials included in the review reported a significant finding on healing with the EMT group. The first study included 44 participants and reported that significantly more ulcers healed in the EMT group when compared to the sham-EMT group; however, the authors reported there were a number of participants that were lost to follow-up making it challenging to determine significance in wound healing. The second study comprised 31 participants and reported a significantly greater reduction in ulcer size in the EMT group; however, the authors reported this result was likely influenced by the differences in prognostic profiles of the treatment groups. The third study included in the review found no significant difference in healing. Based on these findings, the authors concluded that it is unclear whether EMT therapy influences the rate of healing of venous leg ulcers; therefore, further research is needed to determine the efficacy of EMT treatment on wounds.

Kuffler (2015) published results from a review that examined the different standards and novel techniques that have been tested for eliminating pressure ulcers. Electrical stimulation was included in the review, and the author reported that although different types of electrical stimulation have been used to promote wound healing these studies are limited due to the lack of high-quality well designed studies. Therefore, more high-quality studies are needed to determine the efficacy of electrical stimulation on wound healing.

The National (NICE) published a SR that evaluated the effectiveness of electrotherapy for pressure ulcers. Fourteen studies were included. NICE concluded the studies had methodological limitations, including small sample sizes. NICE therefore does not recommend electrotherapy for pressure ulcers, unless part of a clinical trial.

Barnes (2014) published the only SR to date which pooled study findings from RCTs evaluating the effectiveness of electrical stimulation for chronic ulcers of any etiology compared with standard treatment and/or sham stimulation. Twenty-one trials were included in the review; 14 used pulsed currents, five used alternating currents, and two used direct currents. Types of ulcers examined were pressure ulcers in 11 studies, venous ulcers in three studies, diabetic ulcers in two studies, arterial ulcers in one study, and ulcers of mixed etiology in the remaining four studies. Only five of the 21 trials were rated as ‘good’ quality i.e., a score of 4 or 5 on the Jadad scale. Studies generally did not report the clinically important outcomes of percent completely healed or time to complete healing. Instead, they tended to report outcomes related to the decrease in the size of wounds. Meta-analyses were performed on several of these secondary outcomes. A pooled analysis of six studies with a total of 201 patients found that electrical simulation increased the mean percentage change in ulcer size by 24% to 62% compared with standard care and/or sham stimulation. The difference between
groups was statistically significant, \( p<0.001 \), and heterogeneity among trials was not significant. Another pooled analysis of six RCTs with a total of 266 patients found that electrical stimulation resulted in a significantly greater reduction in mean absolute ulcer size compared with standard care and/or sham stimulation. The mean difference in size between groups was 2.42 cm\(^2\) (95% confidence interval [CI], 1.66 to 3.17, \( p<0.001 \)) and there was significant heterogeneity. The authors conducted sensitivity analyses and the significant benefit of electrical stimulation on ulcer size remained when studies on pulsed current and direct current were analyzed separately. Limitations of the evidence evaluated in the review include few high-quality studies, variability in study designs, and lack of data on complete healing.

Other SRs were less comprehensive and did not conduct quantitative meta-analyses. A 2014 SR by Kawasaki et al addressed electrical stimulation only for pressure ulcers.[7] The authors identified seven RCTs and two observational studies that included at least 15 patients. The authors found the greatest amount of support for high-voltage pulsed current.

Another SR, by Liu (2014), identified six RCTs evaluating electrical stimulation for treating pressure ulcers in people with spinal cord injuries.[8] Both reviews concluded that electrical simulation was effective for wound healing. Conclusions were largely based on secondary outcomes reported in studies such as change in wound size and interface pressure, rather than on complete healing.

The Agency for Healthcare Research and Quality (AHRQ) (2013) published a comparative effectiveness review to evaluate the optimal treatment strategy for pressure ulcers.[9] 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.

Additional SRs have been identified which assessed the effects of electrical stimulation upon wound healing; however, all of these reviews were limited by a lack of large, long-term RCTs with which to conduct robust pooled analyses of study findings.[10-16] In addition, the results of these published reviews provided conflicting results, with some reporting no difference between groups.

**RANDOMIZED CONTROLLED TRIALS**

Liu (2016) published a SR assessing of electrical stimulation settings affect pressure ulcer wound healing for patients with spinal cord injuries.[17] The SR evaluated six RCTs and two nonrandomized clinical controlled trials (CCTs). The study concluded pulsed direct current ES on pressure ulcers was more efficacious than constant direct current ES. ES increased wound healing and pressure ulcers receiving ES were less likely to worsen. The authors concluded
that well-designed clinical trials involving larger sample sizes need to determine the optimal benefit on health-outcomes.

Polak (2016) published a RCT evaluating the effectiveness of high-voltage monophasic pulsed current (HVMPC) on stage II and III pressure ulcers. Twenty-five patients received electrical stimulation (ES) for 50 minutes five times a week for six weeks and an additional 24 patients received sham treatments during that time. Wound surface area was evaluated at one week and six weeks. The ES group showed significant improvement over sham treatments, but the authors concluded there were methodological limitations with this study including customization of patient care, short study timeframe, and the fact there were no stage IV pressure ulcers. Further studies are needed to determine the efficacy of this treatment.

Franek (2012) published an RCT that investigated the effects of high-voltage electrical stimulation (HVES) on nonhealing, lower-extremity, stage II and stage III pressure ulcers.[18] 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, five 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 six-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.

Ud-Dine (2012) conducted a small randomized study on electrical stimulation treatment for acute cutaneous wounds.[19] 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.

Houghton (2010) published an RCT on a small (n=34) RCT comparing pressure wound healing (as measured by reduction in wound size at three months) with and without use of electrical stimulation on a group of patients with spinal cord injury in a community-based home setting.[20] Following three 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 six months; no significant difference was found between the treatment groups (six patients in the electrical stimulation group versus five 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.

Adunsky and colleagues (2015) 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.[21] 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 eight 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.

**PRACTICE GUIDELINE SUMMARY**

**AMERICAN COLLEGE OF PHYSICIANS**

The American College of Physicians (ACP) [22] (2015) published guidelines regarding the treatment of pressure ulcers and recommended, “that clinicians use electrical stimulation as adjunctive therapy in patients with pressure ulcers to accelerate wound healing.” However, this was rated as a weak recommendation based upon moderate-quality evidence.

**ASSOCIATION FOR THE ADVANCEMENT OF WOUND CARE**

The Association for the Advancement of Wound Care (AAWC) (2015) published a guideline on care of pressure ulcers,[23] 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 RCT to standard dressing treatment for wounds. The guideline did not address electromagnetic therapy.

**INSTITUTE FOR CLINICAL SYSTEMS IMPROVEMENT**

The Institute for Clinical Systems Improvement (ICSI)[24] (2012) published guidelines regarding pressure ulcer prevention and treatment which indicated, “Electrical stimulation also improves local blood flow and oxygen delivery, has antibacterial effects, helps with debridement and thrombolysis, and decreases pain.” ICSI indicated that electrical stimulation may be considered in the management of pressure ulcers to facilitate wound healing; however, this recommendation was based upon consensus opinion and not in evidence.

**NATIONAL INSTITUTE FOR HEALTHCARE EXCELLENCE (NICE)**

Diabetic foot problems: prevention and management
NICE published a guidance stating do not offer electrical stimulation for diabetic foot ulcers unless part of a clinical trial.[25]

**Pressure Ulcer: prevention and management**

NICE published a guidance stating do not use electrotherapy to treat pressure ulcers in adults unless in a clinical trial.[26]

**WOUND HEALING SOCIETY**

Gould (2016) published updated 2015 guidelines for pressure ulcers.[27] The guidelines state that electrical stimulation may provide healing for pressure ulcers that fail conservative treatments. It is not known what types of electrical stimulation will provide benefit, nor has it been determined which wounds are most likely to respond.

### SUMMARY

There is not enough research to show that electrical stimulation or electromagnetic therapy for the treatment of wounds improves health outcomes. No clinical guidelines based on research recommend electrical stimulation or electromagnetic therapy for wound treatment. Therefore, the use of either electrostimulation or electromagnetic therapy is considered investigational for the treatment of wounds.

### REFERENCES


### CODES

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<td>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</td>
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*Date of Origin: February 2004*