

Electrical Stimulation for the Treatment of Wounds

Effective: September 1, 2023

Next Review: June 2024

Last Review: July 2023

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

Notes:

- Electrical stimulation as a treatment of pain and other musculoskeletal conditions are considered in separate plan Medical Policies.
- Electromagnetic therapy as a treatment of wounds is considered in a separate plan Medical Policy. See Cross References.

Electrical stimulation 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. [Negative Pressure Wound Therapy in the Outpatient Setting](#), Durable Medical Equipment, Policy No. 42
2. [Interferential Current Stimulation](#), Durable Medical Equipment, Policy No. 83.07
3. [Electrical Stimulation for the Treatment of Arthritis](#), Durable Medical Equipment, Policy No. 83.10
4. [Electromagnetic Therapy](#), Durable Medical Equipment, Policy No. 83.13
5. [Non-Contact Ultrasound Treatments for Wounds](#), Medicine, Policy No. 131

BACKGROUND

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.

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)

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, 2] Outcomes relating to the use of a device delivering electrical stimulation 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 AND TECHNOLOGY ASSESSMENTS

Szołtys-Brzezowska (2023) published a systematic review (SR) of randomized clinical trials (RCT) that used electrical stimulation (ES) to treat pressure injuries (PI).^[3] A total of 16 RCTs were included in the review. High-voltage monophasic pulsed current (HVMPC) in 10 trials, low-voltage monophasic pulsed current in two trials, three trials tested a low-voltage biphasic pulsed current, and one trial used low-intensity direct current. The quality of studies included was mostly low to moderate (six low, eight medium and two rated as high quality). Most of the RCTs provided evidence recommending the use of HVMPC. Of note was the consistency of methodology among the 10 trials that employed HVMPC. The usefulness of LVMPC, LVMB, and low-intensity DC was confirmed by only a few trials. The ES sessions in the trials were mostly performed by medical staff at medical and rehabilitation centers, but the authors of three RCTs^{36,43,47} demonstrated that ES is also feasible at patients' homes. The authors concluded that the effect of HVMPC in the treatment of PIs has been most thoroughly investigated in clinical trials. The quality of studies included were mostly low to moderate (six low, eight medium and two rated as high quality).

Zheng (2022) published a SR with meta-analysis of ES in the treatment of patients with diabetes-related ulcers.^[4] The review included data from 352 patients across 10 randomized controlled trials published between 1992 and 2021. Median follow-up period of the studies ranged from 4 to 12 weeks. The percentage of ulcer area reduction was significantly greater in patients treated with ES than in those treated with standard care or placebo (SMD=2.56, 95% CI: 1.43–3.69; $p < 0.001$ (Q-test), $I^2=93.9\%$). In addition, compared to the control group, the relative risk of non-healing rates for the ES group was 0.72 (95% CI: 0.54–0.96; $p=0.38$ (Q-test), $I^2=2.3\%$). Risk of bias as assessed with the revised Cochrane risk-of-bias tool for randomized trials found two studies, four studies, and four studies with low risk of bias, some concerns, and high risk of bias, respectively. Sources of risk for bias included selecting reported results due to lack of protocol information or trial registration (7 of 10 studies) and randomization (6 of 10 studies). Assessment of adverse events was not provided. Larger trials are needed to overcome the limitations of available data on ES for the treatment of patients with diabetes-related ulcers.

A 2020 Cochrane SR with meta-analysis was published which evaluated the potential benefits and harms of ES for treating pressure ulcers.^[5] Twenty studies (N=913) were included. ES was administered for a median (interquartile range (IQR) duration of five (4 to 8) hours per week. Most of the pressure ulcers were on the sacral and coccygeal region (30%), and most were stage III (45%). Half the studies were at risk of performance and detection bias and 25% were at risk of attrition and selective reporting bias. The authors reported that ES may be associated with an excess of, or difference in, adverse events, as evaluated across 13 studies with 586 participants (602 pressure ulcers). Data for adverse events were not pooled but the types of reported adverse events included skin redness, itchy skin, dizziness and delusions, deterioration of the pressure ulcer, limb amputation, and occasionally death. Results of the review were that ES probably increases the proportion of pressure ulcers healed and the rate of pressure ulcer healing (moderate certainty evidence), but its effect on time to complete healing is uncertain compared with no ES (very low certainty evidence). It was unclear whether ES decreases the surface area of pressure ulcers. The authors concluded that the evidence to

date is insufficient to support the widespread use of ES for pressure ulcers outside of a research setting and called for future research to focus on large-scale trials to determine the effect of ES on all key outcomes.

A SR by Girgis and Duarte (2018) assessed the efficacy and safety of high-voltage monophasic pulsed current (HVMP) to treat stage II-IV pressure ulcers.^[6] Of the 11 eligible studies (N=483), nine were RCTs and two were case series. Only level 1 evidence RCTs were included in the meta-analysis. Five studies were included in the quantitative analysis (treatment arm n=137; control arm n=139). All studies found HVMP had positive effects on wound surface area reduction and incidence of complete healing. The percentage of wound surface area reduction per week was 12.39% (95% CI, 10.43-14.37) for HVMP plus standard wound care (SWC) and 6.96% (95% CI, 5.56-8.38) for SWC alone or SWC plus sham HVMP. The net effect of HVMP was 5.4% per week (an increase of 78% greater than SWC alone or SWC plus sham HVMP). Of studies that reported adverse reactions to HVMP, none were seen in five studies and minor adverse reactions were seen in one study. The authors concluded that HVMP was considered relatively safe with rare adverse reactions.

A 2017 Health Technology Assessment completed by Health Quality Ontario evaluated the effectiveness of adding electrical stimulation to standard wound care for pressure injuries.^[7] Nine randomized controlled trials and two non-randomized controlled trials were identified. No significant difference in complete pressure injury healing was identified between adjunct electrical stimulation and standard wound care. Pooled data from four studies indicated electrical stimulation was significantly superior for wound surface area reduction, although GRADE quality of evidence was low. Overall, electrical stimulation was found to be safe to use (GRADE quality of evidence: high), but it is unclear whether it improves wound healing (GRADE quality of evidence: low).

A 2017 meta-analysis by Khouri included 29 randomized trials (total N=1510 patients; total N=1753 ulcers) of individuals treated with electrostimulation, sham stimulation, or standardized wound care.^[8] The primary finding was a highly heterogeneous overall standardized mean difference (SMD) of 0.72 (95% CI, 0.48 to 1; I²=78%). Modalities were varied: in 18 studies, active electrostimulation was placed near the wound, and in 17 studies, electrostimulation was placed over the wound; additionally, types of waveform varied between studies (types included direct, high, or low voltage current, and alternating current). Electrostimulation had greatest efficacy when the active electrode was over the wound and high-voltage pulsed current was used (SMD=0.8; 95% CI, 0.38 to 1.21; I²=79%). Other factors that may have affected the efficacy of electrostimulation were ulcer type, size, and duration (small, quick-healing pressure ulcers were favorable), although the association was not statistically significant (p=0.28). In subgroup analyses, reviewers found a greater sensitivity for wound size area than for other outcomes. Potential sources of heterogeneity were electrode polarity, ulcer etiology, and type of outcome. Reviewers noted that 52% of the studies had a high risk of bias, but concluded that the overall safety and efficacy of electrostimulation seem confirmed, given the current evidence.

A SR by Lala (2016) addressed electrostimulation for treating pressure ulcers in individuals with spinal cord injury.^[9] Fifteen studies met inclusion criteria; six were RCTs, six were prospective controlled trials, two were retrospective controlled trials, and four were case series. Several studies, published by the same research group and using the same populations, might have overlapped. Reviewers used a 10-point methodologic quality score and judged the overall quality of the controlled studies to be low (mean quality score 5.3). A pooled analysis

was conducted of data from four RCTs that reported healing rate. In the pooled analysis, pressure ulcer healing was significantly higher with electrostimulation than sham stimulation or usual care (relative risk, 1.55; 95% CI, 1.12 to 2.15). Several other pooled analyses assessed outcomes related to wound size (of less clinical interest) and data from nonrandomized studies. Sample sizes were small; two of the four RCTs included fewer than 20 patients.

Kuffler (2015) published results from a review that examined the different standards and novel techniques that have been tested for eliminating pressure ulcers.^[10] 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 Institute for Health and Care Excellence (NICE) published a SR that evaluated the effectiveness of electrotherapy for pressure ulcers.^[11] 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.^[12] 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 stimulation 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 cm² (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.

Liu (2016) published a SR assessing of electrical stimulation settings affect pressure ulcer wound healing for patients with spinal cord injuries.^[13] The SR evaluated six RCTs and two nonrandomized clinical controlled trials. 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.

A 2014 SR by Kawasaki addressed electrical stimulation only for pressure ulcers.^[14] 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.^[15] Both reviews concluded that electrical stimulation 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.^[16] 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 on 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.^[17-23] In addition, the results of these published reviews provided conflicting results, with some reporting no difference between groups.

RANDOMIZED CONTROLLED TRIALS

Ibrahim (2019) published a RCT of 45 patients with partial-thickness thermal burn injuries covering 25-40% of total body surface area.^[24] Patients were randomized into equal groups receiving negative pressure wound therapy (NPWT), microcurrent electrical stimulation (MES), or standard wound care. All groups received the same traditional physical therapy programme in addition to the same nursing and medical care. In all groups, wound surface area and colony count were measured 72 hours after burn injury, after 10 days and again at 21 days from the beginning of the study. At 10- and 21-day follow-up, the MES group had a significant reduction in wound surface area compared to the control group ($p < 0.001$). At day 21, the MES group had a significantly lower mean bacterial count than the control group ($p < 0.001$). Larger studies with longer follow-up times are needed to determine the net health benefit of MES in wound care.

In 2017, Polak conducted an RCT in which 63 patients were randomized to cathodal or anodal electrostimulation with high-voltage monophasic pulsed current (HVMPC) or sham stimulation.^[25] All patients had pressure ulcers of 0.5 cm² or greater on the pelvic girdle, and most patients ($n=49$; 77.78%) were immobile; also, regardless of the regimen administered, standard wound care was given to all patients. Of patients who received HVMPC, 23 were given daily 50-minute treatments of cathodal electrostimulation five times per week for six

weeks; a comparator group (n=20) was given cathodal stimulation for one outcomes was observed between cathodal and cathodal-anodal groups, although outcomes in both groups were significantly superior to those for the group receiving sham stimulation. Decreases in wound size area of 82.34% and 70.77% for the cathodal and cathodal-anodal groups, respectively, were significantly larger than the decrease observed in the placebo group (40.53%). Similarly, the HVMPG groups achieved a 50% decrease in wound size area faster (1.92 weeks and 2.60 weeks) than the sham group (10.60 weeks). During the six weeks of treatment, 47.83% of wounds treated with cathodal stimulation closed, as did 45% of those treated with cathodal-anodal stimulation. For the sham group, none of the patients achieved full wound closure at six weeks. This result suggests that the active stimulation protocols were comparable in efficacy and superior to standard wound care. Limitations of the study were that the authors did not confirm blinding rates or follow patients to complete wound closure, so the optimal treatment time was not determined.

Polak (2016) published a RCT evaluating the effectiveness of high-voltage monophasic pulsed current (HVMPG) 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.

Adunsky (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.^[26] 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.

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.^[27] 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 μ s; 100 Hz) continuously for 50 minutes a day, five times/week. Fifty-seven patients were recruited over a four-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 six-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.^[28] 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.^[29] 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.

SUMMARY

The evidence on the use of electrostimulation to treat wounds includes multiple SRs with RCTs and other study designs. Many studies on use of electrical stimulation reported short-term outcomes such as wound healing rate or decrease in wound size; several of the included trials found improvements for these outcomes. However, few studies evaluated complete healing or time to complete healing, two clinically important outcomes. Systematic reviews were limited by the inclusion of studies with poor methodological quality and high heterogeneity. The evidence is insufficient to determine the effects of the technology on health outcomes.

The reviews on use of electromagnetic therapy were limited by the inclusion of small studies and a lack of robust pooled analyses. The one RCT was on this topic focused primarily on postoperative pain, with wound healing being a secondary outcome that was assessed according to a previous protocol. The evidence on the use of electromagnetic therapy to treat wounds is inadequate to support conclusions about efficacy.

PRACTICE GUIDELINE SUMMARY

The American College of Physicians (ACP)^[30] (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 published guidelines (2015) on the care of venous ulcers that included electrostimulation and electromagnetic stimulation as treatment modalities.^[31] These recommendations were with “moderate” strength of recommendation. The AAWC also published a guideline (2010) for the care of pressure ulcers.^[32] 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.

NATIONAL INSTITUTE FOR HEALTHCARE EXCELLENCE

Diabetic foot problems: prevention and management

The National Institute for Healthcare Excellence (NICE) published guidance stating do not offer electrical stimulation for diabetic foot ulcers unless part of a clinical trial.^[33]

Pressure Ulcer: prevention and management

NICE published guidance stating do not use electrotherapy to treat pressure ulcers in adults unless in a clinical trial.^[11]

WOUND HEALING SOCIETY

Gould (2016) published updated 2015 guidelines for pressure ulcers.^[34] 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 for the treatment of wounds improves health outcomes. No clinical guidelines based on research recommend electrical stimulation for wound treatment. Therefore, the use of either electrostimulation is considered investigational for the treatment of wounds.

REFERENCES

1. Guidance for industry: chronic cutaneous ulcer and burn wounds-developing products for treatment. *Wound Repair Regen.* 2001;9(4):258-68. PMID: 11679134
2. Polak A, Kloth LC, Blaszcak E, et al. Evaluation of the Healing Progress of Pressure Ulcers Treated with Cathodal High-Voltage Monophasic Pulsed Current: Results of a Prospective, Double-blind, Randomized Clinical Trial. *Adv Skin Wound Care.* 2016;29:447-59. PMID: 27632442

3. Szołtyś-Brzezowska B, Bańkowska A, Piejko L, et al. Electrical Stimulation in the Treatment of Pressure Injuries: A Systematic Review of Clinical Trials. *Adv Skin Wound Care*. 2023;36(6):292-302. PMID: 37212564
4. Zheng Y, Du X, Yin L, et al. Effect of electrical stimulation on patients with diabetes-related ulcers: a systematic review and meta-analysis. *BMC Endocr Disord*. 2022;22(1):112. PMID: 35477391
5. Arora M, Harvey LA, Glinsky JV, et al. Electrical stimulation for treating pressure ulcers. *Cochrane Database Syst Rev*. 2020;1:CD012196. PMID: 31962369
6. Girgis B, Duarte JA. High Voltage Monophasic Pulsed Current (HVMP) for stage II-IV pressure ulcer healing. A systematic review and meta-analysis. *Journal of tissue viability*. 2018;27(4):274-84. PMID: 30177421
7. Electrical Stimulation for Pressure Injuries: A Health Technology Assessment. *Ontario health technology assessment series*. 2017;17(14):1-106. PMID: 29201261
8. 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*. 2017;25(5):883-91. PMID: 29052946
9. 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. *International wound journal*. 2016;13(6):1214-26. PMID: 25869151
10. Kuffler DP. Improving the ability to eliminate wounds and pressure ulcers. *Wound Repair Regen*. 2015;23(3):312-7. PMID: 25801293
11. Pressure Ulcer Management. April 2014 [cited 6/26/2023]. 'Available from:' <https://www.nice.org.uk/guidance/cg179/evidence/full-guideline-management-pdf-547610510>.
12. 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. *European journal of clinical investigation*. 2014;44(4):429-40. PMID: 24456185
13. Liu L, Moody J, Gall A. A Quantitative, Pooled Analysis and Systematic Review of Controlled Trials on the Impact of Electrical Stimulation Settings and Placement on Pressure Ulcer Healing Rates in Persons With Spinal Cord Injuries. *Ostomy/wound management*. 2016;62(7):16-34. PMID: 27428563
14. 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*. 2014;22(2):161-73. PMID: 24372691
15. 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. *The journal of spinal cord medicine*. 2014;37(6):703-18. PMID: 24969965
16. Agency for Healthcare Research and Quality (AHRQ). Executive Summary. May 8, 2013. Pressure Ulcer Treatment Strategies: Comparative Effectiveness. [cited 6/26/2023]. 'Available from:' <http://www.effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1492>.
17. 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/metabolism research and reviews*. 2012;28 Suppl 1:119-41. PMID: 22271737
18. Aziz Z, Flemming K, Cullum NA, et al. Electromagnetic therapy for treating pressure ulcers. *Cochrane Database Syst Rev*. 2010(11):CD002930. PMID: 21069672
19. Aziz Z, Cullum NA, Flemming K. Electromagnetic therapy for treating venous leg ulcers. *Cochrane Database Syst Rev*. 2011(3):CD002933. PMID: 21412880

20. Aziz Z, Flemming K. Electromagnetic therapy for treating pressure ulcers. *Cochrane Database Syst Rev.* 2012;12:CD002930. PMID: 23235593
21. Aziz Z, Cullum N, Flemming K. Electromagnetic therapy for treating venous leg ulcers. *Cochrane Database Syst Rev.* 2013;2:CD002933. PMID: 23450536
22. Ravaghi H, Flemming K, Cullum N, et al. Electromagnetic therapy for treating venous leg ulcers. *Cochrane Database Syst Rev.* 2006(2):CD002933. PMID: 16625565
23. Olyaei Manesh A, Flemming K, Cullum NA, et al. Electromagnetic therapy for treating pressure ulcers. *Cochrane Database Syst Rev.* 2006(2):CD002930. PMID: 16625564
24. Ibrahim ZM, Waked IS, Ibrahim O. Negative pressure wound therapy versus microcurrent electrical stimulation in wound healing in burns. *Journal of wound care.* 2019;28(4):214-19. PMID: 30975055
25. Polak A, Kloth LC, Blaszczyk 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.* 2017;97(8):777-89. PMID: 28789467
26. Adunsky A, Ohry A. 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. PMID: 15998547
27. 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 management.* 2012;58(3):30-44. PMID: 22391955
28. Ud-Din S, Perry D, Giddings P, et al. Electrical stimulation increases blood flow and haemoglobin levels in acute cutaneous wounds without affecting wound closure time: evidenced by non-invasive assessment of temporal biopsy wounds in human volunteers. *Experimental dermatology.* 2012;21(10):758-64. PMID: 23078397
29. 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. PMID: 20434602
30. 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.* 2015;162:370-9. PMID: 25732279
31. Association for the Advancement of Wound Care (AAWC) International Consolidated Venous Ulcer Guideline (ICVUG) 2015. [cited 6/26/2023]. 'Available from:' <https://aawconline.memberclicks.net/assets/appendix%20c%20guideline%20icvug-textformatrecommendations-final%20v42%20changessaved18aug17.pdf>.
32. Association for the Advancement of Wound Care (AAWC) Guideline of Pressure Ulcer Guidelines. [cited 6/26/2023]. 'Available from:' <https://s3.amazonaws.com/aawc-new/memberclicks/AAWCPressureUlcerGuidelineofGuidelinesAug11.pdf>.
33. Diabetic foot problems: prevention and management. October 2019 [cited 6/26/2023]. 'Available from:' <https://www.nice.org.uk/guidance/ng19>.
34. Gould L, Stuntz M, Giovannelli M, et al. Wound Healing Society 2015 update on guidelines for pressure ulcers. *Wound Repair Regen.* 2016;24(1):145-62. PMID: 26683529

CODES

Codes	Number	Description
CPT	None	

Codes	Number	Description
HCPCS	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

Date of Origin: February 2004