

# ELECTRICAL STIMULATION AND ELECTROMAGNETIC THERAPY FOR WOUNDS

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[Instructions for Use](#) ⓘ

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## Related Medical Management Guideline

- [Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation](#)

## COVERAGE RATIONALE

**Electrical stimulation is proven and medically necessary for treating [Stage III or IV](#) pressure ulcers that have failed to demonstrate [Measurable Signs of Healing](#) with 30 days of conventional treatment which includes ALL of the following:**

- Application of dressings to maintain a moist wound environment; and
- Debridement of necrotic tissue, if present; and
- Evaluation of and provision for adequate nutritional status; and
- Appropriate turning and positioning; and
- Use of a pressure-reducing support surface; and
- Moisture and incontinence management.

**The following are unproven and not medically necessary due to insufficient evidence of efficacy:**

- Electrical stimulation for treating ALL other wounds or ulcers, including but not limited to:
  - Diabetic ulcers
  - Venous stasis ulcers
- Electromagnetic therapy for treating wounds or ulcers including but not limited to:
  - Venous stasis ulcers
  - Arterial ulcers
  - Diabetic foot ulcers
  - Chronic pressure sores
  - Soft tissue injuries

## DOCUMENTATION REQUIREMENTS

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

**Electrical Stimulation and Electromagnetic Therapy for Wounds**

Medical notes documenting **all** of the following:

- Current prescription from physician
- Diagnosis
- Wound stage and size
- Prior treatment duration and response
- Plan of treatment

**DEFINITIONS**

**Measurable Signs of Healing:** Wound is diminishing in size (either surface or depth) and there is decreased amount of exudate and necrotic tissue (National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA), 2014).

**Pressure Ulcer Staging (National Pressure Ulcer Advisory Panel (NPUAP) Staging System):**

Stage III - characterized by full-thickness loss of skin, in which fat is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed.

Stage IV - characterized by full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location.

**APPLICABLE CODES**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
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 therapy, 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

**DESCRIPTION OF SERVICES**

Electrical stimulation involves the application of electrical current through electrodes placed on the skin near the wound and to the saline-moistened gauze placed over the wound. The saline provides a conductive medium that allows electric current to pass directly through the wound. The intent of electrical stimulation is to facilitate the healing of chronic wounds by promoting angiogenesis, collagen synthesis, proliferation of fibroblasts, and migration of epithelial cells. Chronic wounds are defined as wounds that do not heal completely after 30 days (Lazarus et al., 1994).

Electromagnetic therapy refers to the application of electromagnetic fields to the wound area, rather than direct application of electrical current. This procedure is also referred to as pulsed electromagnetic induction (PEMI), pulsed electromagnetic field (PEMF), and pulsed electromagnetic therapy.

### **Reports Evaluating Electrical Stimulation and Electromagnetic Therapy**

In an Agency for Healthcare Quality and Research (AHRQ) report, Saha et al. (2013) compared the safety and effectiveness of treatment strategies for adults with pressure ulcers. Studies published between January 1985 and October 2012 were included. Moderate strength evidence from nine studies (n=397) showed that electrical stimulation improved healing rates; however, evidence about the effect of electrical stimulation on complete wound healing was insufficient because of heterogeneous findings across studies. There was no significant wound improvement with electromagnetic therapy. The authors reported that most studies were of poor quality and had follow-up periods inadequate to assess complete wound healing. Studies often measured healing outcomes using heterogeneous methods, making it difficult to compare results across studies. There was limited evidence to draw firm conclusions about the best approaches for treating pressure ulcers, a finding consistent with other recent reviews on this topic. Future research with larger sample sizes, more rigorous adherence to methodological standards for clinical trials, longer follow-up periods and more standardized and clinically meaningful outcome measures is needed to inform clinical practice and policy.

The International Working Group of the Diabetic Foot (IWGDF) published an update to the 2012 systematic review on the management of diabetic foot ulcers. Studies published between June 2010 and June 2014 were included in the review. Selected studies fell into several categories which included electrical and electromagnetic therapy. Heterogeneity of studies prevented pooled analysis of results. The authors reported similar conclusions as the earlier review. There is little published evidence to justify the use of electrical and electromagnetic therapy for managing diabetic foot ulcers. The authors also noted that analysis of the evidence continues to present difficulties in this field as controlled studies remain few and the majority continue to be of poor methodological quality (Game et al., 2016).

### **Electrical Stimulation**

Khouri et al. (2017) conducted an effect size meta-analysis to assess the overall efficacy of electrical stimulation (ES) on wound healing, to compare the efficacy of the different modalities of electrical stimulation, and to determine whether efficacy differs depending on the wound etiology, size, and age of the chronic wound. Twenty-nine randomized clinical trials with 1,510 patients and 1,753 ulcers were included in the review. Overall efficacy of ES on wound healing was a 0.72 SMD corresponding to a moderate to large effect size. The reviewers found that unidirectional high voltage pulsed current (HVPC) with the active electrode over the wound was the best evidence-based protocol to improve wound healing with a 0.8 SMD, while evaluation of the efficacy of direct current was limited by the small number of studies. ES was more effective on pressure ulcers compared to venous and diabetic ulcers, and efficacy trended to be inversely associated with the wound size and duration. According to the reviewers, this analysis confirms the overall efficacy of ES to enhance healing of chronic wounds and highlights the superiority of HVPC over other type of currents, which is more effective on pressure ulcers, and inversely associated with the wound size and duration.

Houghton (2017) conducted a systematic review to evaluate the effect of electrical stimulation therapy (EST) on wound healing outcomes in adults with various types of chronic wounds. A systematic and comprehensive search of four electronic databases and gray literature was carried out, and references included in related review articles were checked. Prospective and controlled clinical trials, systematic reviews (SRs), and meta-analyses that assessed the effects of EST on wound healing outcomes were described and appraised. A total PRISMA score was assigned for each included SR based on criteria included in the assessment of multiple systematic reviews (AMSTAR) measurement tool. The percentage of available research that was identified in the SR was also calculated. Sixty-two clinical research studies involving 2082 patients with pressure ulcers, venous leg ulcers, diabetic foot wounds, and arterial/ischemic wounds, and ulcers of mixed etiology were identified. Thirty-three of the studies with 1370 patients compared wound size reduction after EST to a control group. Eighteen reviews that used a systematic approach to identify, select, and evaluate published studies on this topic have yielded conflicting results. Poorer quality SRs with a low total PRISMA score were more likely to yield negative or inconclusive findings. Most of these low-quality SRs had very vague research questions and included less than 50% of the available literature that was known to exist. Results from 22 well-designed randomized clinical trials and 10 high-quality SRs consistently support that EST can stimulate faster wound size reduction and/or produce a greater number of closed wounds compared to a group of similar patients receiving either standard wound care or sham EST. The author concluded that pooled results from well-conducted SRs provide strong support for the use of EST on various types of chronic wounds and pressure ulcers in particular. According to the author, there is only one well designed SR that supports the use of EST on diabetic foot wounds and no good review that has compiled the research that is known to exist for EST of venous leg ulcers.

In a systematic review, Ashrafi et al. (2017) provided a detailed update on the variety of electrical stimulation modalities used in the management of lower extremity wounds. Forty-three studies were included in the review. According to the reviewers, pulsed current appears superior to other electrical modalities available. The majority of studies support the beneficial effects of pulsed current over conservative management of lower extremity cutaneous wounds. Although it appears to have no benefit over causal surgical intervention, it is a treatment option which could

be utilized in those patients unsuitable for surgery. The reviewers stated that there is a lack of high-quality studies available to judge confidently the effect of pulsed current on arterial and pressure wounds, and further robust trials are necessary to identify the optimal pulsed current waveform. Other waveforms and modalities appear promising; however, they still lack large trial data to recommend a firm conclusion with regards to their use. Current studies also vary in quantity, quality and protocol across the different modalities. According to the reviewers, the ideal electrical stimulation device needs to be non-invasive, portable and cost-effective and provides minimal interference with patients' daily life. The reviewers stated that further studies are necessary to establish the ideal electrical stimulation modality, parameters, method of delivery and duration of treatment.

Liu et al. (2016) conducted a systematic review to critically appraise and synthesize updated evidence on the impact of electrical stimulation (ES) versus standard wound care (comprising cleansing, dressing, nutrition, and debridement as necessary) and/or sham stimulation on pressure ulcers (PrU) healing rates in persons with spinal cord injuries (SCIs). Included studies were limited to peer-reviewed, randomized controlled trials (RCTs) and non-RCTs (CCTs) published in English from 1985 to 2014. A total of 8 trials were reviewed - 6 RCTs and 2 CCTs included a total of 517 SCI participants who had at least 1 PrU. The number of patients per study ranged from 7 to 150 and the number of wounds from 7 to 192. Comparison models included ES irrespective of current type and placement of electrodes against sham/no ES (7 trials), ES delivered by electrodes overlaid on the ulcer versus sham/no ES (4 trials), ES delivered by electrodes placed on intact skin around the ulcer versus sham/no ES (4 trials), ES delivered by electrodes overlaid on the wound bed versus placed on intact skin around the ulcer (1 trial), ES with pulsed current versus sham/no ES (6 trials), ES with constant current versus sham/no ES (2 trials), pulsed current ES versus constant current ES (1 trial), number of PrUs closed (2 trials), and incidence of PrU worsened by ES versus sham/no ES (2 trials). The overall quality of studies was moderate; 2 trials were rated as good quality, 2 were poor quality, and 4 were moderate. Evidence showed ES increased the rate of PrU healing in patients with SCI (n = 7 studies and 559 ulcers), and a higher proportion of ulcers healed (n = 2 studies and 226 ulcers). The data suggest pulsed current ES increased the healing rate (n = 6 studies and 509 ulcers) more than constant current (n = 2 studies and 200 ulcers). In addition, wounds with electrodes overlaying the wound bed seemed to heal the ulcer faster than wounds with electrodes placed on intact skin around the ulcer. According to the authors, future preclinical, in vivo models and clinical trials examining the impact of electrodes configuration for PrU healing are warranted. The authors indicated that the small number of relevant trials, together with substantial heterogeneity in this review, made it difficult to interpret some findings and draw firm conclusions. Higher heterogeneities evident across the trials in this review can be explained by the variation of study design and stimulation parameters (stimulation frequency, intensity, waveform) and stimulation device used.

Lala et al. (2016) conducted a systematic review and meta-analysis on the effects of electrical stimulation therapy (EST) on healing pressure ulcers in individuals with spinal cord injury (SCI). Studies were included if EST was used to treat pressure ulcers in individuals with SCI. A total of 15 studies met the inclusion criteria. A meta-analysis with five studies demonstrated that EST significantly decreased the ulcer size by 1.32%/day compared to standard wound care (SWC) or sham EST. Another meta-analysis conducted with four studies showed that EST increased the risk of wound healing by 1.55 times compared with standard wound care or sham EST. Because of the wide array of outcome measures across studies, a single meta-analysis could not be conducted. According to the authors, EST appears to be an effective adjunctive therapy to accelerate and increase pressure ulcer closure in individuals with SCI. The authors indicated that there were a number of limitations in this review. There were a relatively limited number of studies that met the inclusion criteria and in general, the sample size of participants was small in each study. In addition, the authors indicated that the meta-analysis findings should be interpreted carefully because of the low methodological quality of the studies and high heterogeneity across some of the studies. Barnes et al. (2014) conducted a systematic review to investigate the effect of electrical stimulation on ulcer healing compared to usual treatment and/or sham stimulation. This systematic review also investigated the effect of different types of electrical stimulation on ulcer size reduction. Databases were searched for randomized controlled trials (RCTs), in English and on human subjects, which assessed the effect of electrical stimulation on ulcer size as compared to standard care and/or sham stimulation. Data from included RCTs were pooled with use of fixed and random effects meta-analysis of the weighted mean change differences between the comparator groups. Heterogeneity across studies was assessed with the I<sup>2</sup> statistic. Twenty-one studies were eligible for inclusion in the meta-analysis. In six trials (n = 210), electrical stimulation improved mean percentage change in ulcer size over total studies periods by 24.62% with no heterogeneity. In three trials (n = 176), electrical stimulation insignificantly improved mean weekly change in ulcer size by 1.64% with significant heterogeneity. In six trials (n = 266), electrical stimulation decreased ulcer size by 2.42 cm (2) with significant heterogeneity. In one trial (n = 16), electrical stimulation also insignificantly improved the mean daily percentage change in ulcer size by 0.63% with significant heterogeneity. The methodological quality of the included trials ranged from poor to good, with a median Jadad score of 3 (range 1–5). The authors concluded that electrical stimulation appears to increase the rate of ulcer healing and may be superior to standard care for ulcer treatment. According to the authors, while electrical stimulation can improve ulcer healing, the inconsistencies in the protocols, as seen in this meta-analysis, make decisions regarding its use complicated. The authors state that it is not possible to establish the relative effectiveness of each treatment protocol as too many variables exist including type of current applied, duration of therapy and ulcer etiology. According to the authors, the limitations of this meta-analysis include

the high heterogeneity among included studies, the poor to moderate methodological quality and the variability of measurements of ulcer healing and electrical stimulation used.

Kawasaki et al. (2014) conducted a systematic review of the efficacy of electrical stimulation in healing pressure ulcer and reviewed its mechanism of action. Databases were searched for relevant interventional studies including randomized controlled trials (RCTs) and observational studies. A best-evidence synthesis was performed to summarize the results of the included studies. A total of seven RCTs and two observational studies met the inclusion criteria. Moderate level of evidence of efficacy with low risk of bias was shown in all seven RCTs. Although some studies have used continuous direct current, most other investigators opted to use high-voltage pulsed current to minimize the risk of skin burn and to achieve greater current penetration. Overall, the incidence of adverse effects was very low. The authors concluded that the mechanisms through which electrical stimulation exerts a positive effect on pressure ulcer healing are reasonably well established. According to the authors, clinical trials have revealed a moderate level of evidence to support its use as an ancillary treatment modality for healing pressure ulcer. The studies included in the review were assessed using the GRADE system and were downgraded for not meeting the optimal information size or not having adequate sample size.

Smith et al. (2013) summarized the evidence comparing the effectiveness and safety of treatment strategies for adults with pressure ulcers. Randomized trials and comparative observational studies of treatments for pressure ulcers in adults and non-comparative intervention series ( $n > 50$ ) for surgical interventions and evaluation of harms were included in the review. Moderately consistent results from 1 good-quality and 8 fair-quality trials showed that electrical stimulation improved healing rates (moderate-strength evidence) but evidence about the effect of electrical stimulation on complete wound healing was insufficient because of heterogeneous findings across studies. The authors concluded that in comparison with standard care, placebo, or sham interventions, electrical stimulation (9 studies [ $n = 397$ ]; moderate consistency) improved healing of pressure ulcers. Low-strength evidence showed that the most common adverse effect of electrical stimulation was local skin irritation and that harms were more common in frail elderly populations than in younger populations. The authors state that applicability of results is limited by study quality, heterogeneity in methods and outcomes, and inadequate duration to assess complete wound healing.

Gomes et al. (2018) evaluated high-voltage electrical stimulation of the donor sites of 30 burn patients treated by grafting surgery. Subjects were randomized into two groups: electrical stimulation (GES), treated with electrostimulation (50min, 100Hz, twin pulses 15 us, monophasic), and the sham group (GS), treated by the same procedures but without current. Pain was assessed by visual analog scale daily before and after the electrical stimulation. The time elapsed until complete epithelization was evaluated (time of primary dressing detached spontaneously). Skin temperature was measured by thermography. The characteristics of donor sites were qualitatively evaluated using images and the plug-in CaPAS<sup>®</sup> (Carotid Plaque Analysis Software). The results showed a significant decrease in pain, which was absent on the third day in the GES and the sixth day in the GS. The time the primary dressing detached spontaneously in days decreased compared to the GS group. Donor site healing characteristics such as vascularization, pigmentation, height, the quantity of crust formed, irregularities, and the quality of healing was better in the GES; moreover, homogeneity and inertia of the images confirmed higher healing quality. The authors concluded that electrical stimulation of donor site wounds shows promise. These findings require confirmation in larger studies with objective assessments and different physical variables.

Polak et al. (2018) conducted a randomized, controlled, double-blind clinical study to evaluate the effects of cathodal and anodal high-voltage monophasic pulsed current (HVMP) electrical stimulation (ES) on periwound skin blood flow (PSBF) and size reduction of pressure ulcers (PUs) of at least 4 weeks' duration. Persons older than 18 years of age, hospitalized with neurological injuries, at high risk for PU development, and with at least one Stage 2 to Stage 4 PU were eligible to participate in the study. Patients were randomly assigned to 1 of 3 groups: anodal (AG), cathodal (CG), or placebo (PG) ES. All groups received individualized PU prevention and standard wound care. In the PG, sham ES was applied; the AG and CG were treated with anodal and cathodal HVMP, 50 minutes per day, 5 days per week, for a maximum of 8 weeks. Nonlinear approximation based on exponential function was used to calculate treatment time needed to reduce the wound area by 50%. Of the 61 participating patients, 20 were in the AG, 21 in the CG, and 20 in the PG. PUs (baseline size range 1.01 cm<sup>2</sup> to 59.57 cm<sup>2</sup>; duration 4 to 48 weeks) were most frequently located in the sacral region (73.77%) and classified as Stage 3 (62.29%). PSBF at week 2 was significantly higher in the AG and CG than in the PG. Week 4 differences were not statistically significant. Wound percentage area reduction calculated at week 8 for the AG and CG were significantly different from PG ulcers. In both ES groups, PSBF at week 4 and percent wound surface area reductions between weeks 4 and 8 were positively correlated, but only the AG correlation was statistically significant. The authors concluded that both ES modalities improved blood flow and wound area reduction rate. The authors stated that additional studies are necessary to examine optimal ES treatment times for healing to occur, the effect of comorbidities and baseline wound variables on ES outcomes, and the nature of the relationship between blood flow and healing.

Polak et al. (2016b) conducted a parallel-group, randomized, single-blind, prospective, controlled clinical trial to determine whether the rate of change in the area of older patients' pressure ulcers (PUs) can be accelerated by using



high-frequency ultrasound (HFUS) and electrical stimulation with high-voltage monophasic pulsed current (HVMP). Patients were randomly assigned to receive either standard wound care (SWC) involving supportive care and topical treatments; SWC+ ultrasound (US); or SWC+ electrical stimulation (ES). The US and ES were administered once a day, 5 days a week. The primary outcome was change in PU surface area measured against baseline after 6 weeks of treatment. A total of 77 patients, aged 60-95 years (80% aged over 70 years of age), with 88 Category II, III and IV PUs were included in the study. The percentage reduction in the surface area of PUs at the end of treatment was significantly greater in the SWC+US group and the SWC+ES group versus the control group. The SWC+ES group also had a significantly greater proportion of PUs that decreased in area by at least 50% or closed than the control group. The SWC+US and SWC+ES groups were not statistically significant different regarding treatment results. The authors concluded that the results show that HFUS and HVMP are comparable regarding their effectiveness in reducing the size of PUs in older people. These findings require confirmation in larger studies.

In a prospective, randomized, controlled, clinical study, Polak et al. (2017) compared the effectiveness of cathodal versus cathodal+anodal electrical stimulation (ES) in the treatment of Category II-IV pressure ulcers (PrUs). Sixty-three participants with PrUs were randomly formed into a cathodal ES group (CG: N = 23; mean age of 79.35), a cathodal+anodal ES group (CAG: N = 20; mean age of 79.65) and a placebo ES group (PG: N = 20; mean age of 76.75). All patients were treated with standard wound care and high-voltage monophasic pulsed current (HVMP) for 50 minutes per day, 5 times a week, for 6 weeks. The CG, CAG, and PG received, respectively, cathodal, cathodal+anodal, and sham ES through electrodes placed on a moist gauze pad. The treatment electrode was placed on the wound, and the return electrode was positioned on healthy skin at least 20 cm from the PrU. Measurements were made at baseline, and after each of the 6 weeks of treatment. Primary outcome was percentage wound surface area reduction at week 6. Wound surface area decreased in the CG by 82.34% and in the CAG by 70.77%. These reductions were significantly greater than in the PG. The CG and CAG were not statistically significantly different regarding treatment results. The authors concluded that cathodal and cathodal+anodal HVMP similarly reduced the area of Category II-IV PrUs. This study was limited because the time to treatment was insufficient for PrUs to close. Further studies are needed to evaluate the long-term efficacy of PrU treatment with electrical stimulation.

In a prospective, randomized, double-blind, controlled clinical study, Polak et al. (2016a) investigated the effectiveness of high-voltage monophasic pulsed current (HVMP) electrical stimulation as an adjunct to a standard wound care for the treatment of Stage II and III pressure ulcers (PrUs). Patients with PrUs that did not respond to previous treatment for at least 4 weeks were randomly assigned to the electrical stimulation (ES) group (25 patients; mean age of 79.92 ± 8.50 years; mean wound surface area [WSA] of 10.58 ± 10.57 cm) or to the control group (24 patients; mean age of 76.33 ± 12.74 years; mean WSA of 9.71 ± 6.70 cm). Both the ES and control groups received standard wound care and respectively, cathodal HVMP (154 microseconds; 100 pulses per second; 0.24 A; 250 μ/s) applied continuously for 50 minutes once a day, 5 times a week, or sham HVMP. The percentage area reduction over 6 weeks of intervention was evaluated. In the ES group, there was a statistically significant decrease in WSA after 1 week of treatment (35% ± 30.5%) compared with 17.07% ± 34.13% in the control group. After treatment, at week 6, percentage area reduction in the ES group was 80.31% ± 29.02% versus 54.65% ± 42.65% in the control group. The authors concluded that cathodal HVMP reduces the WSA of Stage II and III PrUs. According to the authors, further RCTs are necessary to establish the efficacy of anodal and cathodal HVMP applied independently and consecutively, as well as to determine the optimal parameters of this electric field signal. The 6-week treatment program (determined by average length of patient stay in the facility) was not long enough for all PrUs to heal. Consequently, it is not possible to conclude how long HVMP should be applied for Stage II and III PrUs to close. Results enabling the evaluation of the long-term efficacy of PrU treatment are not presented for several reasons; primarily, after the trial ended some patients were discharged and returned to their homes or were transferred to other wards to be treated for concomitant diseases.

A clinical practice guideline for the prevention and treatment of pressure ulcers developed by the National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA) makes the following recommendations:

- Consider the use of electrical stimulation for anatomical locations at risk of pressure ulcer development in spinal cord injury patients. (Strength of Evidence = C)
- Consider the use of direct contact (capacitive) electrical stimulation to facilitate wound healing in recalcitrant Category/Stage II pressure ulcers as well as any Category/Stage III and IV pressure ulcers. (Strength of Evidence = A)
- Consider the use of pulsed electromagnetic field (PEMF) treatment for recalcitrant Category/Stage II pressure ulcers as well as any Category/Stage III and IV pressure ulcers. (Strength of Evidence = C)
- The health professional should use clinical judgment to assess signs of healing such as decreasing amount of exudate, decreasing wound size, and improvement in wound bed tissue. (Strength of Evidence = C)

The NPUAP guideline includes statements about implementation of an individualized continence management plan and prompt cleansing following incontinence episodes.

The strength of evidence in the NPUAP guideline is defined as follows:

- A: The recommendation is supported by direct scientific evidence from properly designed and implemented controlled trials on pressure ulcers in humans (or humans at risk for pressure ulcers), providing statistical results that consistently support the recommendation (Level 1 studies required)
- B: The recommendation is supported by direct scientific evidence from properly designed and implemented clinical series on pressure ulcers in humans (or humans at risk for pressure ulcers) providing statistical results that consistently support the recommendation. (Level 2, 3, 4, 5 studies)
- C: The recommendation is supported by indirect evidence (e.g., studies in healthy humans, humans with other types of chronic wounds, animal models) and/or expert opinion

(National Pressure Ulcer Advisory Panel (NPUAP), European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA), 2014)

In a diabetic foot problems: prevention and management clinical guideline, the National Institute for Health and Care Excellence (NICE) recommended that electrical stimulation therapy should not be offered as an adjunctive treatment for diabetic foot problems unless part of a clinical trial (NICE, 2015; Last updated January 2016).

In a pressure ulcer prevention and management clinical guideline, the National Institute for Health and Care Excellence (NICE) indicated that it does not recommend electrotherapy for pressure ulcers (NICE, 2014).

### **Electromagnetic Therapy**

Smith et al. (2013) summarized the evidence comparing the effectiveness and safety of treatment strategies for adults with pressure ulcers. Randomized trials and comparative observational studies of treatments for pressure ulcers in adults and non-comparative intervention series (n > 50) for surgical interventions and evaluation of harms were included in the review. The authors found that electromagnetic therapy was no different from sham treatment or standard care in wound-healing outcomes.

In a randomized, double-blinded study, Czyn et al. (2012) investigated the benefits of electromagnetic energy in eyelid wound healing in 57 patients who underwent upper blepharoplasty. There was no difference in patient pain rating when comparing placebo with the electromagnetic energy patch. Patients reported 6% less edema and 10% less ecchymosis with the active patch eye than in control eye. The authors concluded that the use of pulsed electromagnetic energy did not have an effect on postoperative pain, edema, or ecchymosis as rated by patients and physicians. The authors noted that there was a statistically significant reduction in physician-graded erythema for active patch eyes versus placebo. The significance of these results is limited by an extremely small sample size. These findings require confirmation in a larger study.

Gupta et al. (2009) assessed the effectiveness of pulsed electromagnetic field therapy (PEMF) in the healing of pressure ulcers in patients with neurological disorders in a randomized double blind control trial. The study included 12 patients (M:F, 9:3) with pressure ulcers who were 12-50 years of age. Six patients with 13 ulcers received PEMF therapy and the remaining 6 patients with 11 ulcers received sham treatment, for 30 sessions (45 minutes each) using the equipment 'Pulsatron'. The frequency of PEMF was set at 1 Hz with sine waves and current intensity of 30 milli ampere. Whole body exposure was given in both the groups. Bates-Jensen wound assessment tool (BJWAT) score National Pressure Ulcer Advisory Panel (NPUAP) scores were used as outcome measures. Thirteen ulcers were in stage IV and 11 were in stage III at the start of the study. Significant healing of ulcers was noted, BJWAT scores, in both the treatment and sham groups at the completion of the study. However, when comparing between the groups, healing was not significant. A similar trend was noted with NPUAP scores with no significant difference between the treatment and sham groups at the completion of study. The investigators concluded that no significant difference in pressure ulcer healing was observed between PEMF treatment and sham group in this study.

In a Cochrane review, Aziz et al. (2011) assessed the effects of electromagnetic therapy (EMT) on the healing of venous leg ulcers. Three randomized controlled trials (RCTs) of variable quality involving 94 people were included in the review. All the trials compared the use of EMT with sham-EMT. In the two trials that reported healing rates; one small trial (44 participants) reported that significantly more ulcers healed in the EMT group than the sham-EMT group however this result was not robust to different assumptions about the outcomes of participants who were lost to follow-up. The second trial that reported numbers of ulcers healed found no significant difference in healing. The third trial was also small (31 participants) and reported significantly greater reductions in ulcer size in the EMT group however this result may have been influenced by differences in the prognostic profiles of the treatment groups. The authors concluded that there is no high quality evidence that electromagnetic therapy increases the rate of healing of venous leg ulcers, and further research is needed. A 2013 update and 2015 update did not identify any new trials that would change the earlier conclusions (Aziz et al., 2013, Aziz and Cullum, 2015).

In another Cochrane review, Aziz et al. (2010) assessed the effects of EMT on the healing of pressure ulcers. Two randomized controlled trials (RCTs), involving 60 participants, at unclear risk of bias were included in the review. Both trials compared the use of EMT with sham EMT, although one of the trials included a third arm in which only standard

therapy was applied. Neither study found a statistically significant difference in complete healing in people treated with EMT compared with those in the control group. According to the authors, the results provide no strong evidence of benefit in using EMT to treat pressure ulcers. However, the possibility of a beneficial or harmful effect cannot be ruled out because there were only two included trials, both with methodological limitations and small numbers of participants. The authors state that further research is recommended. A 2012 update and 2015 update did not identify any new trials that would change the earlier conclusions (Aziz et al., 2012; Aziz and Bell-Syer, 2015).

## **Professional Societies**

### ***The American College of Physicians (ACP)***

The ACP developed a guideline to present the evidence and provide clinical recommendations based on the comparative effectiveness of treatments of pressure ulcers. The guideline was based on published literature on this topic. The guideline graded the quality of evidence and strength of recommendations by using ACP's clinical practice guidelines grading system. Based on the evidence, the ACP recommends that clinicians use electrical stimulation as adjunctive therapy in patients with pressure ulcers to accelerate wound healing (Grade: weak recommendation, moderate-quality evidence). According to the ACP, moderate-quality evidence supports the use of electrical stimulation in addition to standard treatment because it has been shown to accelerate the healing rate of stage 2 to 4 ulcers. Standard or conventional treatment of pressure ulcers includes support surfaces, repositioning, nutritional support, protection of the wound from contamination, and promotion of tissue healing by using debridement and wound cleansing (Qaseem et al. 2015).

## **U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

The FDA has not approved any electrical stimulation or electromagnetic devices specifically for the treatment of chronic wounds. Use of these devices for wound healing is an off-label indication.

The FDA regulates electrical stimulation devices as Class II devices, and more than 500 of these devices have been approved by the FDA 510(k) process. To locate marketing clearance information for a specific device or manufacturer, search the Center for Devices and Radiological Health (CDRH) 510(k) database <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm> or the Premarket Approval (PMA) database <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm> by product and/or manufacturer name. (Accessed October 16, 2018)

## **Electromagnetic Therapy Devices**

The Diapulse® device is classified by the FDA as "diathermy, shortwave, for use other than applying therapeutic deep heat" and received a device class 3 license in 1987. In 1991, the FDA notified the Diapulse Corporation that their device may only be marketed as adjunctive therapy in the palliative treatment of postoperative edema and pain in superficial soft tissue. It has not been approved by the FDA for the treatment of chronic wounds. This means the manufacturer may not market the device for wound healing although this does not prohibit physicians and other healthcare providers from providing this therapy for unapproved uses. The SofPulse™ device is also classified under "diathermy, shortwave, for use other than applying therapeutic deep heat" and received a device class 3 license in 1996.

The Provant® Wound Closure System utilizes the Regensis Model 42, classified by the FDA as a short-wave diathermy device. It received 510(k) approval in October 1997 for use in the palliative treatment of postoperative pain and edema in superficial soft tissue. According to the FDA, this device applies electromagnetic energy to the body and is substantially equivalent to the SofPulse device.

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## GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
09/01/2019	<p><b>Template Update</b></p> <ul style="list-style-type: none"> <li>• Added <i>Documentation Requirements</i> section</li> </ul>
02/01/2019	<ul style="list-style-type: none"> <li>• Reorganized policy template:               <ul style="list-style-type: none"> <li>○ Simplified and relocated <i>Instructions for Use</i></li> <li>○ Removed <i>Benefit Considerations</i> section</li> </ul> </li> <li>• Revised and reformatted coverage rationale:               <ul style="list-style-type: none"> <li>○ Simplified content</li> <li>○ Added language to indicate electrical stimulation is proven and medically necessary for treating Stage III or IV pressure ulcers that have failed to demonstrate Measurable Signs of Healing with 30 days of conventional treatment, which includes all of the following:                   <ul style="list-style-type: none"> <li>▪ Application of dressings to maintain a moist wound environment; and</li> <li>▪ Debridement of necrotic tissue, if present; and</li> <li>▪ Evaluation of and provision for adequate nutritional status; and</li> <li>▪ Appropriate turning and positioning; and</li> <li>▪ Use of a pressure-reducing support surface; and</li> <li>▪ Moisture and incontinence management</li> </ul> </li> <li>○ Removed language indicating electrical stimulation is unproven and not medically necessary for treating arterial ulcers and chronic pressure sores</li> </ul> </li> <li>• Added definition of:               <ul style="list-style-type: none"> <li>○ Measurable Signs of Healing</li> <li>○ Pressure Ulcer Staging [National Pressure Ulcer Advisory Panel (NPUAP) Staging System]</li> </ul> </li> <li>• Updated list of applicable HCPCS codes; revised description for G0295</li> <li>• Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references</li> <li>• Archived previous policy version MMG03.E</li> </ul>

## INSTRUCTIONS FOR USE

This Medical Management Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Management Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare West Medical Management Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

Member benefit coverage and limitations may vary based on the member's benefit plan Health Plan coverage provided by or through UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare Benefits of Texas, Inc., or UnitedHealthcare of Washington, Inc.