

ELECTRICAL STIMULATION AND ELECTROMAGNETIC THERAPY FOR WOUNDS

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Related Policy

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

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care 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.

APPLICABLE LINES OF BUSINESS/PRODUCTS

This policy applies to Oxford Commercial plan membership.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

NON-COVERAGE RATIONALE

Electrical stimulation is unproven and not medically necessary for treating wounds including venous stasis ulcers, arterial ulcers, diabetic foot ulcers, and chronic pressure sores.

There is insufficient evidence from randomized, controlled trials that electrical stimulation, as an adjunct to standard wound care, can increase the healing rate of chronic dermal or cutaneous wounds. There were substantial methodological flaws in the available studies, which make it difficult to define the magnitude of treatment effects and to determine what types of wounds are most likely to benefit from electrical stimulation. There is also insufficient evidence to determine the type of device or form of electrical current for use in wound healing.

Electromagnetic therapy is unproven and not medically necessary for treating wounds including venous stasis ulcers, arterial ulcers, diabetic foot ulcers, chronic pressure sores and soft tissue injuries.

The available evidence regarding the use of pulsed high-frequency electromagnetic energy for the treatment of chronic wounds and soft tissue injuries is insufficient to support conclusions regarding the efficacy of this technology. The data from clinical trials are insufficient to prove efficacy, to define optimal treatment protocols, to establish patient selection criteria, or to evaluate the relative efficacy of this therapy compared with other treatment options. The available studies involved small numbers of subjects and because significant differences were noted between intervention and control groups, it is not possible to draw valid conclusions about the efficacy of this technology.

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 policy 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 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 G0239 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 wound healing by promoting angiogenesis, collagen synthesis, proliferation of fibroblasts, and migration of epithelial cells.

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.

CLINICAL EVIDENCE

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. 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

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 I² 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.

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. (2016) investigated the effectiveness of high-voltage monophasic pulsed current (HVMPC) 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 HVMPC (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 HVMPC. 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 ($35\% \pm 30.5\%$) compared with $17.07\% \pm 34.13\%$ in the control group. After treatment, at week 6, percentage area reduction in the ES group was $80.31\% \pm 29.02\%$ versus $54.65\% \pm 42.65\%$ in the control group. The authors concluded that cathodal HVMPC 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 HVMPC 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 HVMPC 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.

In a prospective, randomized, controlled clinical study, Franek et al. (2012) evaluated the effect of high-voltage electrical stimulation (HVES) on nonhealing, lower-extremity Stage II and Stage III pressure ulcers. Patients admitted for care and eligible to participate in the study received standard supportive care and topical treatments covered with wet-to-moist dressings. Patients assigned to the treatment arm of the study also received HVES continuously for 50 minutes once daily, five times per week. Patients were followed until healing for a maximum of 6 weeks. Wound tracings and measurements were obtained weekly. Over a 4-year period, 26 patients were enrolled in the treatment and 24 in the control group. Ulcers had existed for an average of 3.17 and 2.83 months in the treatment and control groups, respectively. Wound areas and linear measurements decreased significantly in both groups, but increases in granulation tissue were significant in the treatment group only. Wound area, linear measurement, wound volume, and granulation tissue changes were statistically significantly greater in the treatment than in the control group starting in the second week of treatment. Week 6 surface area change was 88.9% in the treatment and 44.4% in the control group. According to the authors, HVES improved the healing rate of recalcitrant Stage II and Stage III pressure ulcers. The authors stated that research to compare the effectiveness of using cathodic and anodal stimulation combined or alone and to determine the optimal duration of these two types of electrical stimulation is warranted. The authors noted that the study length (4 years) could have introduced some variability in methods and procedures. Although study outcomes were consistent in each treatment group, the absence of blinding and use of placebo ES in the control group is a limitation of this study that may affect the generalizability of the findings.

Magnoni et al. (2013) investigated the effectiveness of an electrical stimulation (ES) therapy as adjuvant treatment for chronic wounds of various etiologies, in terms of pain and ulcer healing. A total of 60 patients with chronic limb ulcers were enrolled for the study and randomized into the intervention ($n=30$) or control group ($n=30$). The intervention group received conventional treatment plus Frequency Rhythmic Electrical Modulation System (FREMS), while the control group received only conventional treatment. Each ES treatment cycle consisted of 12 sessions performed in 4 weeks (three sessions/week). All patients were treated until full wound healing occurred, or for a maximum of 9 ES cycles, with a 2-week rest between each cycle. During follow-up, some patients terminated the protocol because they reached the ulcer closure before the maximum of 9 cycles. The analysis of the effect of ES on pain and ulcer healing was performed on all patients who underwent at least two consecutive clinical evaluations (two cycles). In order to reach a compatible sample size with the primary objective (one patient withdrew). In both groups, there was a significant reduction of pain compared with baseline starting from T6 visit in the first cycle. In particular, there was a significant reduction of pain in the intervention group compared with the control group after 14 days, and this reduction continued until the end of the second cycle. Similarly, there was a significant reduction of PUSH tool score in the intervention group compared with the control group after 14 days, and this reduction continued until the end of the second cycle. The authors concluded that data collected in this study suggest that the ES therapy had a positive and significant effect on pain reduction (VAS) and on the improvement of ulcer healing process in terms of the PUSH tool total index compared with conventional treatment, and may have induced a significant acceleration of the wound-healing process. According to the authors, study limitations include the lack of a real sham therapy in the comparator group receiving treatment alone, which limited the ability to assess the cause-and-effect ratio.

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; The guideline indicates that this is a weak positive recommendation)
- 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 strength of evidence in the 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, Czyz 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) 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) (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 a 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/pmnmn.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 24, 2017)

Electromagnetic Energy 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.

Additional Products

The complete list of commercially available devices used to provide electrical stimulation for wound healing is too extensive for inclusion here; however, 2 of the devices used in the studies selected for review are the Tenzcare® stimulator (3M, Minneapolis, MN) and the DynaWave® 12 pulse generator (DynaWave Corp, Geneva, IL).

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2018T0527J]

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
02/01/2018	<ul style="list-style-type: none">Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references; no change to non-coverage rationale or list of applicable codesArchived previous policy version DME 029.14 T2