MEDICAL POLICY

ELECTRICAL STIMULATION AND ELECTROMAGNETIC THERAPY FOR WOUNDS

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COVERAGE RATIONALE

Electrical stimulation is unproven for the treatment of 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 for the treatment of wounds including venous stasis ulcers, arterial ulcers, diabetic foot ulcers, chronic pressure sores and soft tissue injuries.

Related Medical Policies:
- Electrical Stimulation for the Treatment of Pain and Muscle

Related Coverage Determination Guidelines:
- None
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.

**BACKGROUND**

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).

**CLINICAL EVIDENCE**

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 an earlier
systematic review on the management of diabetic foot ulcers. Studies published between
December 2006 and June 2010 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 as well as
reviews by Cochrane and the National Institute for Health and Care Excellence (NICE). 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 presented difficulties in
this field particularly as controlled studies are few and the majority are of poor methodological
quality (Game et al., 2012).

**Electrical Stimulation:**

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.
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.

Houghton et al. (2010) investigated whether electric stimulation therapy (EST) administered as part of a community-based, interdisciplinary wound care program accelerates healing of pressure ulcers in people with spinal cord injury (SCI) in a single-blind, parallel-group, randomized, controlled, clinical trial. Study participants included 34 adults with SCI and stage II to IV pressure ulcers. Patients were stratified based on wound severity and duration and randomly assigned to receive either a customized, community-based standard wound care (SWC) program that included pressure management or the wound care program plus high-voltage pulsed current applied to the wound bed (EST+SWC). Wound healing was measured by reduction in wound size and improvement in wound appearance at 3 months of treatment with EST+SWC or SWC. The percentage decrease in wound surface area (WSA) at the end of the intervention period was significantly greater in the EST+SWC group than in the SWC. The proportion of stage III, IV, or X pressure ulcers improving by at least 50% WSA was significantly greater in the EST+SWC group than in the SWC group. Wound appearance assessed using the photographic wound assessment tool was improved in wounds treated with EST+SWC but not SWC alone. According to the investigators, these results demonstrate that EST can stimulate healing of pressure ulcers of people with SCI. The small study population limits the validity of the conclusion of this study.

Peters et al. (2001) randomized 40 diabetic patients with foot ulcers to electrical stimulation or placebo stimulation applied each night for 12 weeks through an electrically conductive stocking. Differences between the test and control groups in the rates of wound healing were not statistically significant and, although complete healing was observed for 65% of wounds in the test group versus 35% of wounds in the control group, this difference was not statistically significant unless some patients were excluded for poor compliance with the treatment protocol. Baker et al. (1997) randomized 80 diabetic patients with lower extremity ulcers to 3 different electrical stimulation protocols or a control group that underwent only standard wound care. After 5 to 7 weeks, the group of patients who underwent asymmetric electrical stimulation had a mean weekly 27% decrease in wound size versus a 17% mean decrease for the control group and 17% mean decrease for the low-intensity electrical stimulation group. The improved wound healing for the asymmetric electrical stimulation group was statistically significant only when compared with a group composed of the control and low-intensity stimulation groups combined. Other shortcomings of the studies by Peters et al. (2001) and Baker et al. (1997) include 13% and 25% dropout rates, poor patient compliance with treatment protocols, and lack of follow-up data.

In a randomized controlled trial, Jankovic and Binic (2008) examined the effect of frequency rhythmic electrical modulation system (FREMS) on healing of 43 chronic painful leg ulcers in 35 patients. The patients were separated into two random groups, one treated with FREMS and the control group. Comparing the findings of decreased leg ulcer surface, pain, leg ulcer score, score of vicinity with the controls, it was established that FREMS system accelerated ulcer healing, reduced pain and demonstrated better effects compared to the control group. These findings require confirmation in a larger study.

Electrical Stimulation and Electromagnetic Therapy for Wounds: Medical Policy (Effective 02/01/2014)

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Houghton et al. (2003) randomized 27 patients with 42 chronic wounds due to arterial insufficiency, venous insufficiency, or diabetes to 12 sessions of electrical stimulation or placebo stimulation provided over 4 weeks. After treatment, the test group had a decrease in mean ulcer size of 44%, which was statistically significant relative to the 16% decrease in the control group. Compared with the control group, the test group also had statistically significant improvements in a standardized test of wound appearance. However, there were no significant differences between the test and control groups in wound size or appearance after 1 month of follow-up. In addition to small size, the study population was heterogeneous, with a wide range of wound size and duration.

In a randomized double-blinded placebo controlled study, Adunsky and Ohry (2005) evaluated 63 patients with stage 3 pressure ulcers who were treated with electrical stimulation or placebo for 8 weeks and examined at 12 weeks. Complete closure rate and mean time to complete closure were similar in the 2 groups at day 57 (end of treatment) and day 147 (end of follow-up). There was complete wound healing of 25.7% for direct current vs 35.7% for placebo direct current (P=.28) at day 147 (end of follow-up). Absolute ulcer area reduction and speed of wound area reduction (reflected by change from baseline ulcer area, percentage) were better in participants allocated in the treatment group only until day 45. According to the investigators, the results of the study suggest that decubitus direct current treatment for pressure ulcers grade 3 degree, in addition to the conservative wound care, may be useful in accelerating the healing process during the first period of care. Only 38 patients completed the trial (54% of active treatment group and 64% of placebo treated group) making it difficult to interpret the results.

Ogrin et al. (2009) conducted a double blind, placebo controlled randomized trial of low frequency transcutaneous sensory nerve stimulation (LF-SNS) for 5 minutes, twice daily for up to 12 weeks, on healing of chronic venous leg. Four layer compression bandaging was the standard therapy. Patients (mean age 75 years) with chronic venous ulcers were randomly allocated to active nerve stimulation (n=14) or to sham nerve stimulation (n=15). Microvascular blood flow improved in all participants. A high proportion of wounds healed (approximately 60%). There were trends for better C-fibre function and faster healing rates in the active group compared to the sham group but failed to reach statistical significance due to the small sample size. The investigators concluded that the improvement in microvascular blood flow in both groups was an unexpected finding that has not previously been described. Most likely this was due to the four layer compression bandaging provided to all participants. The observed trends to increased healing rates and improvements in C-fibre function in the actively stimulated group compared to the sham group warrant further studies of LF-SNS as an adjunct therapy for chronic venous leg ulcers.

A small study of electrical stimulation for treatment of decubitus ulcers was conducted by Griffin et al. (1991), who randomized 20 patients to daily sessions of true or placebo electrical stimulation and assessed wound size at 5-day intervals. Differences between the test and control groups in wound size were statistically significant on days 5, 15, and 20, and, at the end of the study, the median decrease in wound size was 80% for the test group versus 52% for the control group. Limitations of the study include the following: the study had a very small sample size of all males, adjustments of standard wound care for wound infection was not reported, assessment was not blinded to treatment, and there was no follow-up after post-treatment assessment.

Wood et al. (1993) randomized 71 patients with 74 decubitus ulcers to 24 sessions of true or placebo electrical stimulation treatment provided over 8 weeks and reported that complete healing occurred for 25 (58%) patients in the test group versus 1 (3%) patient in the control group. The investigators concluded that pulsed low-intensity direct current represents a useful approach for the treatment of stage II and stage III chronic decubitus ulcers by increasing the healing rate. This study included the following limitations: the ulcer stage distribution in the electrical stimulation and control groups were not reported; the randomization procedure was not reported; antibiotic use and infection assessment was not reported; length of each electrical stimulation treatment sessions were not reported; 6 (8%) patients died during study; decrease in
wound area reported in graphical not numeric format; and there was no follow-up after post-treatment assessment. This study was funded in part by the device manufacturer.

In a prospective, randomized, single-blinded, sham-controlled clinical trial, Goldman et al. (2004) evaluated if high-voltage pulsed current (HVPC) electrotherapy increased blood flow and wound healing in infrapopliteal ischemic wounds. Six patients were treated for 14 weeks with either active or sham therapy. Wounds decreased more in size and showed better circulation in the treated group. The investigators concluded that the results of the study demonstrate that HVPC decreased the area of ischemic wounds, reversing the expected increase in wound size, and improved microcirculation. According to the investigators, the promising results of this pilot study require a larger Phase II study to confirm and generalize these findings.

Kim et al. (2010) investigated whether sensory (sub-motor-threshold) electrical stimulation (ES) may provide a pressure ulcer preventive intervention in a double-blinded, repeated measures study. Six adult males with complete spinal cord injury (SCI) were randomly assigned to treatment or control groups. The treatment group received the ES intervention, whereas the control group received a control sham intervention. No statistically significant changes before and after treatment were found in regional T(c)PO(2), gluteal muscle area or pressure distribution. Thus, subthreshold ES does not appear to have any sustained effects on tissue health status indicative of reduced pressure ulcer risk for individuals with SCI.

A randomized double blind multi-center study of electric stimulation compared with sham units enrolled 59 patients (67 wounds) with open wounds of pressure, vascular and surgical etiology at nine sites. The 14-week study consisted of a four-week phase, randomized, parallel-group, double blind, sham stimulation controlled group comparing effectiveness and tolerance of electric and sham stimulation of open wounds. Patients with wounds not completely closed at the end of the four weeks were allowed to cross over to actual treatment. After four weeks of treatment, the electric stimulation group showed a 56% decrease in size with only a 33% decrease in size with sham treatment. According to the investigators, the available data suggest that pulsed electric stimulation should be considered by health care practitioners as an adjunct for treating open wounds (Mulder, 1991). Study limitation included a small sample size; diverse causes and duration of wounds; wounds of less than 1 week duration were classified as chronic; data on wounds and patients excluded from study were not reported and were not subjected to intent-to-treat analysis; use of antibiotics and assessment of infection were not reported; outcomes were not reported separately for wounds of different types and duration prior to treatment; and most wounds were not healed completely.

Taradaj et al. (2011) estimated early and long-term results of physical methods in the treatment of venous leg ulcers. In group A after surgical operation, 40 patients were treated with the high-voltage stimulation (HVS) and drug therapy. In group B after operation, 37 patients were treated with ultrasound and drug therapy. In group C after operation, 33 patients were treated with low-level laser therapy (LLLT) and drug therapy. In group D after operation, 35 patients were treated with the compression stockings and drug therapy. In group E after operation, 37 patients were only treated with drug therapy. Group F consisted of 32 patients, conservatively treated with the HVS and drug therapy. Group G consisted of 20 patients, conservatively treated with ultrasound and drug therapy. Group H consisted of 21 patients, conservatively treated with LLLT and drug therapy. Group I consisted of 30 patients, conservatively treated with compression and drug therapy. Group J consisted of 27 patients only treated with drug therapy. Both short and long term parameters showed that compression therapy is the most efficient in ulcer healing. The authors concluded that electrical and ultrasound methods are less effective in reducing the risk of recurrence.

Regan et al. (2009) systematically reviewed evidence on the prevention and treatment of pressure ulcers in those with a spinal cord injury (SCI). To be selected for inclusion in the current review, there had to have been an intervention, studies had to have 3 or more subjects, and 50% or more of the participating group had to have an SCI. The authors concluded that there is limited evidence supporting the use of electrical stimulation and electromagnetic therapy for wound healing.
level 4 evidence (pre-post or post-interventions and case series) that electrical stimulation decreases ischial pressures post-SCI. There is level 4 evidence that electrical stimulation may increase blood flow at sacral and gluteal areas post-SCI. The authors also concluded that there is level 1 evidence from 2 RCTs (Griffin, 1991, n=20; Adegoke and Badmos, 2001, n=7) to support the use of electrical stimulation to accelerate the healing rate of stage III/IV pressure ulcers when combined with standard wound management.

Kloth (2005) conducted a systematic evidence review which focused on both in vivo and in vitro studies of the impact using electrical stimulation to induce increased blood flow, thus improving capillary density to promote healing of chronic wounds. While several studies are described within this review, the author indicates that the use of different types of electrical currents and stimulation parameters make the interpretation of these studies confusing and therefore difficult to draw conclusions from.

Gardner et al. (1999) conducted a meta-analysis to quantify the effect of electrical stimulation on chronic wound healing. Fifteen studies, which included 24 electrical stimulation samples and 15 control samples, were analyzed. The average rate of healing per week was calculated for the electrical stimulation and control samples. Ninety-five percentage confidence intervals were also calculated. The samples were then grouped by type of electrical stimulation device and chronic wound and reanalyzed. Rate of healing per week was 22% for electrical stimulation samples and 9% for control samples. The net effect of electrical stimulation was 13% per week, an increase of 144% over the control rate. The 95% confidence intervals of the electrical stimulation (18-26%) and control samples (3.8-14%) did not overlap. Electrical stimulation was most effective on pressure ulcers (net effect = 13%). Findings regarding the relative effectiveness of different types of electrical stimulation device were inconclusive. The reviewers concluded that although electrical stimulation produces a substantial improvement in the healing of chronic wounds, further research is needed to identify which electrical stimulation devices are most effective and which wounds respond best to this treatment.

Reddy et al. (2008) systematically review published randomized controlled trials (RCTs) evaluating therapies for pressure ulcers. No clear benefit was identified in 21 RCTs evaluating adjunctive therapies including electric current, ultrasound, light therapy, and vacuum therapy.

A clinical practice guideline for the treatment of pressure ulcers developed by the European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel concludes that the use of direct contact (capacitative) electrical stimulation may be considered in the management of recalcitrant Category/Stage II, as well as Category/Stage III and IV pressure ulcers to facilitate wound healing. [Strength of Evidence = 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 guideline statement (Level 1 studies required)] (European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel, 2009).

A clinical practice guideline for pressure ulcer prevention and treatment following spinal cord injury developed by the Consortium for Spinal Cord Medicine concludes that the use electrical stimulation combined with standard wound care interventions promotes closure of stage III or IV pressure ulcers. [Scientific evidence--I/II; Grade of recommendation--A (The guideline recommendation is supported by one or more level I studies); Strength of panel opinion--Strong] (Consortium for Spinal Cord Medicine, Paralyzed Veterans of America Pressure Ulcer Guideline for Spinal Cord Injury, 2000).

In a diabetic inpatient 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, 2011).

**Electromagnetic Therapy:**

Electrical Stimulation and Electromagnetic Therapy for Wounds: Medical Policy (Effective 02/01/2014)

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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.

Findings reported in earlier randomized controlled trials suggest that pulsed electromagnetic therapy may improve healing rates in venous or pressure ulcers and in the donor site following skin grafting, compared with standard wound care. (Kenkre et al., 1996; Salzberg et al., 1995) Another earlier randomized controlled trial failed to find a significant treatment effect of electromagnetic therapy for patients with chronic venous ulcers, although there was a trend toward improved healing in the intervention group (Todd et al., 1991).

Several earlier randomized controlled studies examined pulsed electromagnetic energy therapy for management of disparate types of soft tissue injuries, including whiplash, ankle sprains, and hand/finger lacerations. (Foley-Nolan et al., 1992; Pennington et al., 1993) In these studies, trends were found toward significant benefit to the intervention groups with respect to swelling, pain, and mobility, particularly when treatment was applied in the acute phase (within 3 to 4 days of injury). However, aside from examining the same technology, the trials differed so much in type of injury and treatment protocol that no overall conclusions regarding the efficacy of pulsed electromagnetic energy therapy can be made.

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 milliampere. 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 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.

Junger et al. (2008) investigated 39 patients in a prospective, placebo-controlled, double blind study on the effect of low-frequency pulsed current (Dermapulse) on healing in chronic venous ulcers. The patients were treated with the Dermapulse or a placebo for 4 months. Ulcer area decreased in both groups, but pain reduction was better in the treated group. These findings require confirmation in a larger 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 did not identify any new trials that would
change the earlier conclusions (Aziz et al., 2013).

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 did not identify any new trials that would change the
earlier conclusions (Aziz et al., 2012).

A 2005 Blue Cross Blue Shield Technology Evaluation Center (TEC) Assessment determined
that the evidence is not sufficient to permit conclusions on the efficacy of electrical stimulation or
electromagnetic therapy as adjunct treatments for wound healing. Well-designed and well-
conducted sham placebo-controlled randomized controlled studies are needed that consistently
show better outcomes for active treatment over placebo. Electrical stimulation and
electromagnetic therapy for chronic wounds did not meet the TEC criteria (Blue Cross Blue Shield
Association, 2005).

Professional Societies
Association for Advancement of Wound Care (AAWC):
In a guideline for venous ulcer care, the AAWC compiled recommendations from 21 venous ulcer
guidelines with the best supporting evidence for each recommendation. The AAWC indicates that
electrical stimulation or electromagnetic/radiofrequency (RF) stimulation may be applied to
venous ulcers if conservative therapy does not work in 30 days (Evidence Level A: Results of two
or more randomized controlled trials (RCTs) in humans provide support (or for diagnostics or risk
analysis: cohort (CO) studies) (AAWC, 2010).

In a guideline for pressure ulcers, the AAWC recommends that if a pressure ulcer is unresponsive
to standard management, electrical stimulation may be used to treat the pressure ulcer (Evidence
Level A: Results of a meta-analysis or two or more pressure ulcer-related randomized controlled
trials on humans provide support) (AAWC, 2010).

American College of Foot and Ankle Surgeons (ACFAS): The ACFAS 2006 diabetic foot
disorders clinical practice guideline states that the rationale for using electrical stimulation in
wound healing stems from the fact that the human body has an endogenous bioelectric system
that enhances healing of bone fractures and soft tissue wounds. According to the ACFAS
guideline, laboratory and clinical studies provide an abundance of support for the use of electrical
stimulation in wound care. This clinical practice guideline is based on the consensus of current
clinical practice and review of the clinical literature (Frykberg et al., 2006).

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. 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

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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 Regenesis 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).

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare covers electrical stimulation (ES) and electromagnetic therapy for the treatment of wounds when criteria are met. Refer to the National Coverage Determination (NCD) for the Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds (270.1). Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Wound Care. (Accessed September 30, 2013)

APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

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<th>HCPCS Code</th>
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<tr>
<td>E0769</td>
<td>Electrical stimulation or electromagnetic wound treatment device, not otherwise classified</td>
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<td>G0281</td>
<td>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</td>
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<td>Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281</td>
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<td>G0295</td>
<td>Electromagnetic stimulation, to one or more areas, for wound care other than described in G0239 or for other uses</td>
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<td>Electromagnetic therapy, to one or more areas for chronic stage III and stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care</td>
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Electrical Stimulation and Electromagnetic Therapy for Wounds: Medical Policy (Effective 02/01/2014)

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**POLICY HISTORY/REVISION INFORMATION**

<table>
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| 02/01/2014 | • Updated description of services to reflect most current clinical evidence, FDA information and references  
• Revised coverage rationale:  
  o Removed coverage criteria for electrical stimulation for the treatment of soft tissue injuries; this indication is addressed in the policy titled *Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation*  
• Archived previous policy version 2013T0527E |