Electrical Stimulation and Electromagnetic Therapy for Wounds (for Louisiana Only)

Policy Number: CS035LA.H
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Instructions for Use

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Application

This Medical Policy only applies to the state of Louisiana.

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
- Appropriate turning and positioning; and
- Debridement of necrotic tissue, if present; and
- Evaluation of and provision for adequate nutritional status; and
- Moisture and incontinence management; and
- Use of a pressure-reducing support surface

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:
  - Arterial ulcers
  - Chronic pressure ulcers
  - Diabetic foot ulcers
  - Soft tissue injuries
  - Venous stasis ulcers

Definitions

Check the definitions within the member benefit plan document that supersede the definitions below.

Measurable Signs of Healing: Wound is diminishing in size (either surface or depth) and there is decreased amount of exudate and necrotic tissue (Gould et al., 2016).

Pressure Ulcer Staging (National Pressure Ulcer Advisory Panel 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 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 federal, state, or contractual requirements 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.

Electrical Stimulation

Pressure Ulcers

Results from randomized controlled trials (RCTs) provide support for the use of electrical stimulation to increase the healing rate of stage III or IV pressure ulcers.

Girgis and Duarte (2018) conducted a systematic review and meta-analysis to determine and quantify the efficacy of high-voltage monophasic pulsed current (HVMPC) in the treatment of stage II-IV pressure ulcers. Nine RCTs and two case series matched the criteria and were included in the systematic review, whereas, only level 1 evidence RCTs were included in the meta-analysis. The percentage of wound surface area reduction per week was 12.39% (95% CI) for HVMPC plus standard wound care (SWC) and 6.96% (95% CI) for SWC alone or SWC plus sham HVMPC. The net effect of HVMPC was 5.4% per week (an increase of 78% greater than SWC alone or SWC plus sham HVMPC). The authors concluded that level 1, 2 and 4 evidence studies consistently indicate that HVMPC plus SWC are more effective than SWC alone or SWC plus sham HVMPC in treating stage II-IV pressure ulcers. According to the authors, level 1 evidence studies show that HVMPC intervention improves the healing of pressure ulcers (reduced wound surface area), and combined with SWC, increases the probability of complete healing and almost eliminates the probability of worsening of healing. HVMPC intervention was shown to be relatively safe, with rare adverse reactions. While patients with stage II pressure ulcers were included in some of the studies in this meta-analysis, the authors did not perform a sub-group analysis specific to stage II pressure ulcers. Therefore, it is unclear if this procedure is effective in for this indication or if the aggregate findings are driven by the effect among patients with stage III and IV pressure ulcers. Polak et al. (2017), Polak et al. (2016a), and Polak et al. (2016b), which were previously cited in this policy, are included in the Girgis and Duarte (2018) systematic review and meta-analysis.

A randomized, controlled, double-blind clinical study conducted by Polak et al. (2018) not included in the above systematic review/meta-analysis, evaluated the effects of cathodal and HVMPC electrical stimulation (ES) on 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 HVMPC, 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 cm2 to 59.57 cm2; duration 4 to 48 weeks) were most frequently located in the sacral region (73.77%) and classified as Stage 3 (62.29%). Periwound skin blood flow (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, periwound skin blood flow (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.

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 would 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.

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. 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.

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) recommends that pulsed current electrical stimulation be administered to facilitate wound healing in recalcitrant category/stage II pressure injuries and category/stage III or IV pressure injuries (strength of evidence = A).The NPUAP guideline includes statements about implementation of an individualized continence management plan and prompt cleansing following incontinence episodes (European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance, 2019).

Diabetic Foot Ulcers and/or Venous Stasis Ulcers

There is limited evidence in the published scientific literature to support the use of electrical stimulation to facilitate healing of all other wounds or ulcers such as diabetic ulcers and venous stasis ulcers. The data from clinical trials for these types of ulcers are insufficient to prove efficacy or to evaluate the effects of this therapy compared with other treatment options.

Chen et al. (2020) performed a meta-analysis to evaluate the effectiveness of electric stimulation (ES) for diabetic foot ulcer (DFU) treatment. The authors searched MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, and ClinicalTrials.gov databases for randomized clinical trials published through March 2019 that compared the efficacy of ES and standard wound care (SWC) versus SWC alone for DFU treatment. The outcomes were pooled using a random-effects model. Of the 145 randomized clinical trials initially identified, seven studies (with a total of 274 patients) met the inclusion criteria. The percentage decrease in ulcer area at 4 weeks was significantly greater in patients treated with ES and SWC than SWC alone (standardized mean difference, 1.09; 95% confidence interval, 0.62-1.57; P < .001). The ulcer healing rate at 12 weeks was also significantly faster in the ES group (risk difference, 0.19; 95% confidence interval, 0.06-0.32; P = .005). Subgroup analysis showed comparable efficacies with different waveforms (monophasic vs biphasic). One study limitation was lack of relevant data, a subgroup analysis of the efficacy of ES for different DFU subtypes (such as different ulcer sites) could not be conducted. This meta-analysis indicates that ES may accelerate DFU healing and may be an effective adjunctive therapy for these complex wounds. More RCTs with larger sample sizes are needed to expansively evaluate the value of ES for DFUs.

Avazzadeh et al. (2020) in a comparative study looked at the hemodynamic performance of two neuromuscular electrical stimulation devices applied to the lower limb. Neuromuscular muscular electrical stimulation can produce adequate increases in lower limb hemodynamics enough to prevent venous stasis. The aim of this study was to measure the hemodynamic changes in the lower limb with the use of two neuromuscular electrical stimulation devices. Twelve healthy volunteers received two neuromuscular stimulation device interventions. The Geko™ and National University of Ireland (NUI) Galway neuromuscular electrical stimulation devices were randomized between dominant and non-dominant legs. Hemodynamic measurements of peak venous velocity (cm/s), the time average mean velocity (TAMEAN) (cm/s), and ejected volume (mL) of blood were recorded. Peak venous velocity was significantly increased by the Geko™ and the NUI Galway device compared to baseline blood flow ($p < 0.0001$), while only the voluntary contraction produced significant increases in TAMEAN and ejected volume (both $p < 0.05$). Both devices tested in this study require further examination to determine their effectiveness at altering hemodynamics to beneficial levels in terms of VLU therapy. This study is limited by the number of participants and the fact that the study was carried out on young health adults. VLUs are more frequently seen in elderly and non-ambulatory patients, as the reduced mobility seen in these groups contributes to underactivation of the calf muscle pump, which can lead to chronic venous insufficiency (CVI). A larger study with age-appropriate controls is required with these devices to determine their effectiveness on limb hemodynamics.

The International Working Group of the Diabetic Foot (IWGDF) published a 2016 update to the 2012 systematic review on the management of diabetic foot ulcers. Selected studies fell into several categories which included electrical therapy. Heterogeneity of studies prevented pooled analysis of results. The authors reported similar conclusions as the earlier review indicating that there is little published evidence to justify the use of electrical 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., 2016a).

An IWGDF guidance on use of interventions to enhance the healing of chronic diabetic ulcers of the foot, recommends the following: do not select agents reported to have an impact on wound healing through alteration of the physical environment, including through the use of electricity, in preference to accepted standards of good quality care (GRADE: strength of recommendation: strong; quality of evidence: low). The IWGDF guidance indicated that studies on the use of electrical stimulation have reported no convincing evidence of benefit for diabetic foot ulcers (Game et al., 2016b).

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 October 2019).

Electromagnetic Therapy

There is limited evidence in the published scientific literature to support the use of electromagnetic therapy for treating chronic wounds and ulcers. The data from clinical trials are insufficient to prove efficacy or to evaluate the effects of this therapy compared with other treatment options.

The International Working Group of the Diabetic Foot (IWGDF) published a 2016 update to the 2012 systematic review on the management of diabetic foot ulcers. Selected studies fell into several categories which included electromagnetic therapy. Heterogeneity of studies prevented pooled analysis of results. The authors reported similar conclusions as the earlier review

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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).

Smith et al. (2013) summarized the evidence comparing the effectiveness and safety of treatment strategies for adults with pressure ulcers. Four randomized trials and comparative observational studies (n = 112) evaluating electromagnetic therapy 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 (p = .11) and 10% less ecchymosis (p = .17) 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.

Professional Societies

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. Low-quality evidence showed no difference or mixed findings for the other adjunctive therapies assessed, including electromagnetic therapy. 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)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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 cleared by the FDA 510(k) process. To locate marketing clearance information for a specific device or manufacturer, search the following Center for Devices and Radiological Health (CDRH) 510(k) database or the Premarket Approval (PMA) database by product and/or manufacturer name:

- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm
- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

(Accessed February 1, 2021)

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 Regenesis Model 42, classified by the FDA as a short-wave diathermy device. It received 510(k) clearance 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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Policy History/Revision Information

Date	Summary of Changes
04/01/2021	**Template Update** • Removed *Related Policies* section • Updated *Instructions for Use*; replaced reference to "MCG™ Care Guidelines" with "InterQual® criteria" **Supporting Information** • Removed *CMS* section • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version CS035LA.G

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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