Electrical Stimulation for Wounds (for Kentucky Only)

Policy Number: CS374KY.01
Effective Date: June 1, 2024

➲ Instructions for Use

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Related Policies

- Electromagnetic Therapy for Wounds (for Kentucky Only)
- Habilitation and Rehabilitation Therapy (Occupational, Physical, and Speech) (for Kentucky Only)

Application

This Medical Policy only applies to the state of Kentucky.

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
- Management of existing infection, if present; and
- Moisture and incontinence management; and
- Use of a pressure-reducing support surface

Electrical stimulation for treating all other wounds or ulcers, is unproven and not medically necessary due to insufficient evidence of efficacy, including but not limited to:

- Diabetic ulcers
- Venous stasis ulcers

Definitions

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
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

Description of Services

Electrical stimulation for accelerating wound healing involves the direct application of at least two electrodes attached to a small battery-like device. The electrical stimulation device provides short bursts of electrical current in varying intervals to the area surrounding the pressure injury. Once applied, the electrical current alters the charge across the wound bed, modifying the cell membrane potential and promoting angiogenesis. (Arora et al. 2020)

Clinical Evidence

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.

Avedano-Coy et al. (2022) conducted a multi-centric, parallel, double-blind, RCT with placebo control to evaluate the efficacy of microcurrent therapy for healing pressure ulcers (PUs) in aged people. The primary purpose of this trial was to determine the effectiveness of standardized nursing-care protocol combined with microcurrent patches 10/h day on the healing process of pressure ulcers. The secondary goal was to analyze the effect of microcurrent therapy on the periulcer blood flow, arterial blood pressure, analgesics intake, capillary glycemia, and ulcer infection. Included in the study were 30 participants randomly divided into two groups (15 received standardized nursing-care protocol combined with microcurrent patches 10h/day daily for 25 days and 15 received standardized nursing-care protocol plus sham stimulation). Along with measuring wound surface, depth and grade, ulcer healing was also measured using the Pressure Ulcer Scale for Healing (PUSH) which ranges from 0 (wound completely healed) to 17 (the worst state of the wound). Evaluations during this study occurred pre-intervention (T1), 14 days following the start of the intervention (T2) and 1 day after intervention completion (T3). PU grades included stage II, III and IV in n = 6 (20%), n = 18 (60%), and n = 6 (20%). Two 10 cm electrodes were applied around the ulcer edge of the dressing. The experimental group received microcurrents that were a monophasic, pulsed, square-form wave pulse of 1.5 s with a 300 mspause, a voltage of 21 mV, the intensity of 42 μA, and the current density of 4.2 μA/cm. The sham group received a sham microcurrent stimulation tested with an oscilloscope to ensure no electric current was emitted. The authors reported improvement at the PUSH at T2 and T3 was 16.8% (CI95% 0.5-33.1) and 25.3% (CI95% 7.6-43.0) greater in the experimental group versus the sham control. Additionally, the authors noted reduction in the wound area at T2 and T3 was 20.1% (CI95% 5.2-35.0) and 28.6% (CI95% 11.9-45.3) greater in the experimental group versus the control. While no complete wound healing occurred in the sham group, it was reported complete healing occurred in n = 3 (20%) participants in the active group. With these reported findings, the authors concluded that microcurrent therapy improved the healing of PUs quantitatively and qualitatively without any adverse consequences.

Chen et al. (2022) performed a systematic review and meta-analysis in an attempt to update the evidence and assessing the efficiency and safety of electrical stimulation (ES) for PU healing, applying no restriction in care setting, parameters,

duration (both ulcers and intervention duration) or types of patients. Seventeen RCTs including 740 patients were included in this study. Meta-analysis of eight RCT's demonstrated that ES significantly reduced the ulcer surface in contrast with standard wound care alone or pulsed sham ES. Nine studies showed that ES increased the risk of PUs being completely healed than the controlled group. Three studies reported that adverse reactions were rare. The meta-analysis results indicated that ES was identified to have statistically significant effect on the overall percentage of wound surface area (WSA) reduction (P = 0.001), reduction in ulcer size (P = 0.02) and the number of healed PUs (P = 0.04). Taken together with descriptive results from this systematic review, ES results in PUs' improvement by healing , reduces the absolute WSA and the percentage of ulcer healing rate. The results were different in polarities of current, health settings of patients, current types, age of patients and duration of PUs, future studies should focus on these areas (Polak 2018, 2017, 2016a and 2016b, which were previously cited in this policy, are included in this review).

Arora et al. (2020) completed a Cochrane review comparing ES plus standard care to sham/no ES plus standard care for the management of PUs. The review included 20 RCTs with a total of 913 patients (mean age range: 26 to 83 years) with PUs ranging from a mean of 4 days to > 12 months. Nineteen studies were conducted in four different settings, including rehabilitation and geriatric hospitals, medical centers, a residential care center, and a community-based center. ES probably increases the proportion of PUs healed compared with no ES (risk ratio (RR) 1.99, 95% confidence interval (CI) 1.39 to 2.85; I2 = 0%; 11 studies, 501 participants (512 PUs)). Most of the PUs were on the sacral and coccygeal region (30%), and most were stage III (45%). Half the studies were at risk of performance and detection bias and 25% were at risk of attrition and selective reporting bias. In conclusion the author indicated that ES probably increases the proportion of PUs healed, but its effect on time to complete healing is uncertain, and the certainty of evidence for all outcomes is moderate, low or very low. The evidence to date is insufficient to support the widespread use of ES for all PUs, additional research is needed to determine the effect of ES in all significant scenarios. (Lala 2016 and Polak 2018 included in this study).

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 PUs. 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 PUs. According to the authors, level 1 evidence studies show that HVMPC intervention improves the healing of PUs (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 PUs were included in some of the studies in this meta-analysis, the authors did not perform a sub-group analysis specific to stage II PUs. 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 PUs. 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 ES on 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, 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 ES on wound healing, to compare the efficacy of the different modalities of ES , and to determine whether efficacy differs depending on the wound etiology, size, and age of the chronic wound. Twenty-nine RCTs 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 PUs 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 PUs, 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 ES 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 ES 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 ES 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 ES versus standard wound care (comprising cleansing, dressing, nutrition, and debridement as necessary) and/or sham stimulation on PU healing rates in persons with spinal cord injuries (SCIs). Included studies were limited to peer-reviewed, 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 PU. 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 PUs closed (2 trials), and incidence of PU 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 PU 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 PUs in individuals with SCI. Studies were included if EST was used to treat (PUs) 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 ES 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 (EPUAP, NPUAP and PPPIA, 2019).

Diabetic Foot Ulcers and/or Venous Stasis Ulcers

There is limited evidence in the published scientific literature to support the use of ES 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.

Girgis et al. (2023) performed a systematic review and meta-analysis to review the effectiveness of HVMPC in the treatment of diabetic ulcers. Twelve RCTs were identified for review and included 30 participants with 35 ulcers in the treatment arm. The control arm included 29 participants with 33 ulcers. Mean age in the treatment arm was 56.85 ±3.46 years old, and in the control was 59.6 ±0.42 years old. Ulcer duration was 19.55 ±0.63 weeks in the treatment arm, while it was 36.45 ±20.43 weeks in the control arm. Mean baseline wound surface area (WSA) was 3.09 ±2.07 cm in the treatment arm, while it was 8.7 ±7.29 cm in the control arm. Intervention period was 14 ±2.82 weeks. The pooled result was RR 1.43; 95% CI: (0.92, 2.24), P = 0.11; I = 7%, P = 0. The authors determined evidence was inconclusive and not strong enough to support the use of HVMPC in the treatment of diabetic ulcers as the primary limitation of this review was the insufficient treatment period allowed for ulcers to completely heal. Additionally, they reported the definition and pathophysiology of pressure ulcers may overlap with diabetic ulcers and further studies are needed.

Borges et al. (2023) conducted a systematic review on the effect of EST in healing venous leg ulcers. The review consisted of eight RCTs and three case series and involved 724 limbs with venous leg ulcers in 716 patients. The mean patient age was 64.2 years (95% confidence interval, 62.3-66.2), and 46.2% (95% confidence interval, 41.2%-50.4%) were men. The active electrode was placed on the wound with the passive electrode placed on healthy skin (n = 6), the two electrodes were placed on either side of the wound edges (n = 4), or a planar probe was used (n = 1). The pulsed current was the most used waveform (n = 9) particularly a high-voltage pulsed current (n = 5), followed by the frequency rhythmic electrical modulation system (n = 1) and a radio electric asymmetric conveyer (n = 1). Different methods were used to measure the outcome of venous leg ulcer (VLU) healing. Eight studies reported changes in ulcer size during the treatment and follow-up periods, six studies reported the ulcer healing rate, and three studies reported the time to healing. Five RCTs detected statistically significant improvement in at least one VLU healing outcome after EST compared with the control groups. All case series demonstrated improvements in the VLU healing outcomes after EST. The authors concluded evidence suggests that a monophasic, pulsed current is the most effective type of EST for wound healing. Additional research to determine the appropriate EST parameters, delivery strategy, and therapy duration is required. There were several study limitations. A small number of studies were included. The protocols varied for conducting the studies which provided a challenge when comparing results. Another limitation was the inability to perform a formal publication bias evaluation. Poor quality of scientific evidence, concern surrounding the randomization aspect in the included RCT's, and lack of prespecified analysis plan were additional limitations reported.

Melotto et al. (2022) conducted a systematic review with the main purpose to collect, present and critically evaluate the current findings available in the literature regarding the effects of ES on diabetic foot ulcers(DFUs) compared with the standard wound care (SWC) alone. ES is a physical-based therapy able to increase cells activity and migration into wound bed as well as inhibiting bacterial activity. Seven articles out of 560 publications met the inclusion criteria. Due to the heterogeneity of the studies a meta-analysis was not performed, the study designs made the comparison of results difficult. Findings showed that healing rate (HR) appears to be higher among diabetic ulcers treated with ES; however, the reliability of these findings is affected by the small sample sizes of the studies. Also, four studies are considered as moderate or high risk of bias. The evidence to suggest the standard use of ES in the treatment of DFUs remains insufficient. Larger more robust studies are needed to confirm these findings.

Zheng et al. (2022) in a systematic review and meta-analysis, authors aimed to systematically review the literature to better understand the efficacy of ES for the treatment of patients with diabetes-related ulcers. Embase, Medline, and Cochrane Library databases were searched through July 31, 2021. Original trials for ES treatment of patients with diabetes-related ulcers with placebo or standard care as the control group were included. 20 articles were selected for full-text review with 10 included in the data quality assessment and data analysis. The main outcomes were ulcer area reduction and healing rates. Meta-analyses were performed to compare the standardized mean difference (SMD) in the percentage of ulcer reduction and risk ratio of non-healing rates between ES treatment and placebo or standard care. Authors used the Revised Cochrane risk-of-bias tool for randomized trials to assess the risk of bias for each included article. Funnel plots and Egger's test were used to assess publication bias. Compared to placebo or standard care, ES had a significant benefit for the treatment of patients with diabetes-related ulcers in terms of percentage of ulcer reduction (SMD = 2.56, 95% CI: 1.43-3.69; P < 0.001 (Q-test), I2 = 93.9%) and ulcer healing rates [risk ratio of non-healing rates for the ES group was 0.72 (95% CI: 0.54-0.96; P = 0.38 (Q-test), I2 = 2.3%)]. Limitations included the following: while ES appeared safe for treating ulcers related to diabetes, there was not sufficient data to evaluate the adverse effects of ES; a meta-regression analysis to explore possible potentiators of ES effects due to the limited data; insufficient data to perform subgroup analysis according to different ulcer types; although all included studies were RCTs, only two studies were categorized as having a low risk of bias. The main limitations focus on lack of protocol information to clarify, no selection

reporting, no information on the generation of randomization, and some concerns in blinding or masking. Thus, the low quality of the evidence could potentially decrease the impact of the current findings. In conclusion, ES could be used to treat patients with diabetes-related ulcers. ES treatment was effective for ulcer area reduction and ulcer healing, although it had a high heterogeneity level among the included studies. Pulsed current ES has the potential benefit of increasing ulcer healing compared to direct current ES. Additional large-scale robust studies are needed to explain the adverse events and potentiators of ES in the treatment of patients with diabetes-related ulcers.

Chen et al. (2020) performed a meta-analysis to evaluate the effectiveness of ES for DFU treatment. The authors searched MEDLINE, EMBASE, Cochrane Central Register of Controlled Trials, and ClinicalTrials.gov databases for RCTs published through March 2019 that compared the efficacy of ES and SWC versus SWC alone for DFU treatment. The outcomes were pooled using a random-effects model. Of the 145 RCTs 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 ES devices applied to the lower limb. Neuromuscular ES 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 ES devices. Twelve healthy volunteers received two neuromuscular stimulation device interventions. The Geko™ and National University of Ireland (NUI) Galway neuromuscular ES 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 DFUs. 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 DFUs. 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 ES have reported no convincing evidence of benefit for DFUs (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 EST should not be offered as an adjunctive treatment for diabetic foot problems unless part of a clinical trial (NICE, 2015; Last updated October 2019).

In a clinical practice guideline from the Society for Vascular Surgery and the American Venous Forum for the management of VLUs, ES for VLUs is not recommended. This is due to few studies that focus solely on VLUs along with inconsistency in the treatment parameters including variability in type of electrical current, settings, treatment times, and preferred waveforms, making comparisons impossible (O'Donnell et al. 2014).

Clinical Practice Guidelines

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 (PUs). 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 (ES) as adjunctive therapy in patients with PUs to accelerate wound healing (Grade: weak recommendation, moderate-quality evidence). According to the ACP, moderate-quality evidence supports the use of ES 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 PUs 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 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 November 8, 2023)

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Policy History/Revision Information

Date	Summary of Changes

06/01/2024	**Title Change/Template Update**
	• Relocated and reformatted content previously included in the Medical Policy titled *Electrical Stimulation and Electromagnetic Therapy for* Wounds (for Kentucky Only)
	Related Policies
	• Added reference link to the Medical Policy titled:
	  ○ *Electromagnetic Therapy for Wounds* (for Kentucky Only)
	  ○ *Habilitation and Rehabilitation Therapy (Occupational, Physical, and Speech)* (for Kentucky Only)
	• Removed reference link to the Medical Policy titled *Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation* (for Kentucky Only)
	Coverage Rationale
	• Revised list of conventional treatments for Stage III or IV pressure ulcers that have failed to demonstrate Measurable Signs of Healing with 30 days; added "management of existing infection, if present"
	Supporting Information
	• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information
	• Archived previous policy version CS035KY.04

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.

UnitedHealthcare uses InterQual® or MCG (Milliman) for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) for substance use, in administering health benefits. If InterQual® or MCG do not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies, Coverage Determination Guidelines, or Utilization Review Guidelines that have been approved by the Kentucky Department for Medicaid Services. The UnitedHealthcare Medical Policies, Coverage Determination Guidelines, or Utilization Review 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.