Electrical Stimulation (ES) for the Treatment of Wounds

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Introduction

Electrical stimulation (ES) for the treatment of wounds is addressed by this guideline.

Criteria

The use of electrical stimulation (ES) for the adjunctive treatment of wounds is considered medically necessary when **all** of the following apply:

- The individual has **any** of the following conditions:
  - chronic stage 3 or stage 4 pressure ulcers
  - arterial ulcers
  - diabetic ulcers
  - venous stasis ulcers
- A wound therapy program has been tried including **all** of the following, and there are no measurable signs of improved healing:
  - The wound has been assessed, measured, and described.
  - Topical dressings appropriate for wound type have been applied.
  - Debridement has been performed to remove necrotic tissue (if present).
  - Treatment or intervention to correct any infection and/or underlying condition that may hinder the healing process has been performed (if needed).
  - Repositioning and mobilization program for offloading of pressure has been tried.
  - Ongoing care of diabetes (for individuals with diabetic ulcers).
  - Establishment of adequate circulation to the wound site has been performed (for individuals with arterial ulcers).
  - Compression bandages and/or garments have been applied (for individuals with venous ulcers).
- The treatment is used in the home and supervised by a medical professional with training and expertise in wound evaluation and management.

Initial Rental

- Initial rental period of one month (30 days).

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Continued Rental

- Continued rental of an electrical stimulation (ES) device is considered medically necessary when **all** of the following apply:
  - There is documentation that the wound is progressing.
  - There is monthly documentation of wound length, width, and depth.
  - There is monthly documentation of proper use of the device and continued benefit.

Rental Period Exceeding Four (4) Months

Use of an electrical stimulation (ES) device for a month exceeding four months in total duration is considered medically necessary when **all** of the following apply:

- There is monthly documentation that wound healing is progressing.
- There is monthly documentation of wound length, width and depth.
- There is monthly documentation of proper use of the device and continued benefit.
- There is monthly documentation of specific and detailed information to explain the continuing problems with the wound and what additional measures are being undertaken to address those problems and promote healing.
- There is monthly documentation of why a switch to alternative treatments alone is not possible.

Discontinuation

Continued coverage of an electrical stimulation (ES) device for wounds and ulcers described in this guideline is not medically necessary when there is documentation of **any** of the following:

- Criteria for continued rental of the device has not been met.
- There is documentation of 100% epithelialized wound bed.
- In the judgment of the treating practitioner, adequate wound healing has occurred to the degree that ES for the treatment of wound(s) may be discontinued.

Definitions

- **Electrical stimulation**, in which a direct current is applied to the wound, has been shown to improve rates of wound healing in wounds demonstrating sufficient granulation tissue. Electrical stimulation is applied to the periwound tissues. The duration and voltage have not been clearly defined. The electric current is provided once or twice daily through a wound overlay and is believed to promote the migration and proliferation of fibroblasts.
- **Chronic ulcers** are defined as ulcers that have not healed within 30 days of occurrence. A chronic ulcer, or non-healing wound, either does not progress through

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an orderly and timely sequence of repair, or the repair process is impaired and does not reach resolution.

- **Pressure ulcers** occur most commonly near the sacrum or ischial tuberosities and may occur in other areas including, but not limited to, the knees, heels, or other bony prominences. Risk factors for skin breakdown and pressure ulcers may include spinal cord injury, increased pressure over bony prominences, asymmetric posture, and extended duration of sitting.
- The National Pressure Injury Advisory Panel (NPIAP) provides a method for classification of pressure injuries. The system is supported by the Wound Ostomy Continence Nurses (WOCN) Society:
  - **Stage 1 pressure injury:** Intact skin with a localized area of non-blanchable erythema, which may appear differently in darkly pigmented skin. Presence of blanchable erythema or changes in sensation, temperature, or firmness may precede visual changes. No purple or maroon discoloration, as these may indicate deep tissue pressure injury.
  - **Stage 2 pressure injury:** Partial-thickness loss of skin with exposed dermis. The wound bed is viable, pink or red, moist, and may present as an intact or ruptured serum-filled blister. Adipose (fat) and deeper tissue are not visible. Granulation tissue, slough, and eschar are not present. These injuries commonly result from adverse microclimate and shear in the skin over the pelvis and shear in the heel. This stage should not be used to describe moisture associated skin damage including incontinence associated dermatitis, intertriginous dermatitis, medical adhesive related skin injury, or traumatic wounds (e.g., skin tears, burns, abrasions).
  - **Stage 3 pressure injury:** Full-thickness skin loss, in which adipose (fat) tissue is visible in the ulcer, and granulation tissue and rolled wound edges are often present. Slough or eschar may be visible. The depth of tissue damage varies by anatomical location; areas of significant adiposity can develop deep wounds. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage, and bone are not exposed. If slough or eschar obscures the extent of tissue loss, this is an unstageable pressure injury.
  - **Stage 4 pressure injury:** Full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage, or bone. Slough or eschar may be visible. Rolled wound edges, undermining, or tunneling often occur. Depth varies by anatomical location. If slough or eschar obscures the extent of tissue loss, this is an unstageable pressure injury.
  - **Unstageable full-thickness pressure injury:** Full-thickness skin and tissue loss in which the extent of tissue damage within the ulcer cannot be confirmed because it is obscured by slough or eschar. If slough or eschar is removed, a stage 3 or stage 4 pressure injury will be revealed. Stable eschar (e.g., dry, adherent,

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intact without erythema or fluctuance) on the heel or ischemic limb should not be softened or removed.
    - **Deep tissue pressure injury (DTPI):** Intact or nonintact skin with localized area of persistent non-blanchable deep red, maroon, or purple discoloration, or epidermal separation revealing a dark wound bed or blood-filled blister. Pain and temperature change often precede skin color changes. Discoloration may appear differently in darkly pigmented skin. This injury results from intense or prolonged pressure and shear forces at the bone-muscle interface. The wound may evolve rapidly to reveal the actual extent of tissue injury or may resolve without tissue loss. If necrotic tissue, subcutaneous tissue, granulation tissue, fascia, muscle, or other underlying structures are visible, this indicates a full-thickness pressure injury (i.e., unstageable, stage 3, or stage 4). DTPI is not used to describe vascular, traumatic, neuropathic, or dermatologic conditions.
- **Arterial ulcers**, or ischemic ulcers, occur most often on the extremities. Poor perfusion starves the overlying tissues of oxygen and nutrients, causing tissue death and open wounds. These wounds are painful and often feature ragged borders, a dry base, and pale or necrotic centers.
- **Diabetic ulcers** are a common complication of advanced diabetes mellitus, and most often occur in the feet. The chronic hyperglycemia of diabetes mellitus can lead to microvascular complications, including diabetic neuropathy and peripheral vascular disease. In diabetic neuropathy, an individual may experience numbness in the distal extremities and a lack of protective sensation, which can lead to injuries that may go unnoticed by the individual, leading to infection.
- **Venous stasis ulcers** may develop due to poor venous circulation in the extremities, often due to impaired valve functioning, blood clots, or venous hypertension. These wounds often feature hard and discolored skin, edema, and/or pus or fluid.

Evidence Discussion

Medical background

- Electrostimulation devices, such as transcutaneous electrical nerve stimulation (TENS) and neuromuscular electrical stimulation (NMES), have been approved by the United States Food and Drug Administration (FDA) for indications relating to pain relief. However, the FDA and the United States Centers for Medicare and Medicaid Services (CMS) have specified that electrical stimulation for wound care is a separate use category. As of 2003, the FDA considered devices used for electrostimulation of wounds to be Class III devices. This classification requires manufacturers to undergo a full Premarket Approval (PMA) process prior to marketing their devices in the United States. At that time, the FDA had not cleared or approved any electrostimulation devices to be used in a wound care setting.

Literature review

- A 2023 randomized controlled trial reported by Zulbaran-Rojas and colleagues examined the effectiveness of daily home-based electrical stimulation (E-stim) therapy to expedite wound healing in patients with chronic diabetic foot ulcers (DFUs). The study randomized 33 patients to an intervention group (one hour of home-based E-Stim therapy using a bio-electric stimulation technology (BEST®) platform (Tennant Biomodulator® PRO) daily for four weeks), or a control group (treatment with an identical but non-functional placebo device). The participants continued adjunctive treatments in addition to standard of care (i.e., topical mupirocin, calcium alginate, and/or wet to dry dressings). The primary outcome included wound area reduction at four weeks. The results of the study demonstrated that the intervention group had a significant reduction in wound area of 22% (P = .002) at four weeks. Wound area reduction was unchanged in the control group (P = .982). In addition, the reported adherence to daily home electrical stimulation therapy was 93.3%. In conclusion, the authors opined that daily home-based electrical stimulation was an effective adjunctive therapy to accelerate wound healing in patients with DFUs.
- Zheng et al., (2022) performed a systematic review and meta-analysis to evaluate the efficacy of electrical stimulation (ES) in the treatment of patients with diabetes-related ulcers. The authors reviewed ten randomized controlled trials including 352 patients that compared ES with a control group or standard of care. The primary outcomes were ulcer area reduction and healing rates. The results of the meta-analyses reported that patients treated with ES had a significant percentage of ulcer area reduction (P < .001) and ulcer healing rates (P < .05) when compared to the control group. In summary, the authors concluded that ES could be used as a treatment for individuals with diabetes-related ulcers in clinical practice.
- Borges et al., (2023) conducted a systematic review to evaluate the efficacy of electric stimulation therapy (EST) in the healing of venous leg ulcers (VLUs). The review included eight randomized controlled trials (RCTs) and three case series involving 716 patients with VLUs. Among the included studies, the primary outcome was ulcer healing. The change in the ulcer size was the main method used to determine ulcer healing (n = 8), followed by the ulcer healing rate (n = 6), exudate levels (n = 4), and the time to healing (n = 3). Compared with the control group, five of eight RCTs detected a statistically significant improvement in at least one VLU healing outcome after EST. In two of the five RCTs demonstrating improved outcomes with EST, the improved healing was only found in patients who had not undergone surgical treatment of VLUs. Moreover, the use of EST led to accelerated wound closure. All case series reported improvements in wound healing outcomes with EST. After EST, the patients' exudate levels decreased compared with the controls, except for patients who had undergone surgery, for whom the exudate levels were similar. Thus, the authors concluded that this study supported the use of EST to accelerate wound healing for VLUs, most notably in patients who were not surgical candidates.

- Chen et al., (2023) conducted a systematic review and meta-analysis to evaluate evidence of the effectiveness and safety of electrical stimulation (ES) for treating pressure ulcers. The study included 17 randomized controlled trials which used electrical stimulation for the treatment of pressure ulcers. When compared with sham ES or standard wound care, ES resulted in a statistically significant reduction in ulcer area ($P < .001$), reduction in ulcer size ($P = .02$), and an increase in the number of healed ulcers ($P = .04$). Based on the results of the study, the authors reported low to moderate evidence that that electrical stimulation could help reduce the absolute wound surface area and increase the ulcer healing rate.
- A 2020 Cochrane review by Arora and colleagues aimed to determine the efficacy of electrical stimulation (ES) for treating pressure ulcers. The review included 20 studies with 913 participants. ES was administered for a median duration of five hours per week. The majority of pressure ulcers were stage 3 (45%) and on the sacral and coccygeal region (30%). The authors reported moderate certainty evidence that ES increases the proportion of pressure ulcers healed compared with no ES (11 studies, 501 participants (512 pressure ulcers)). The effect on time to complete healing and the surface area of pressure ulcers was uncertain (very low certainty evidence). Thus, the authors acknowledged that future research should focus on larger-scale trials to determine the efficacy of ES in the treatment of pressure ulcers.
- Janković and Binić (2008) reported a randomized controlled trial that examined the effect of a frequency rhythmic electrical modulation system (FREMS) on healing of chronic painful leg ulcers. The study included 35 patients randomized into two groups: (1) a group of 20 patients with 24 leg ulcers (20 venous, two arterio-venous, one arterial, and one diabetic leg ulcer) with FREMS treatment, and (2) a control group of 15 patients. The study evaluated parameters of ulcer healing including: wound surface area, wound appearance (fibrin accumulations, exudation, granulation, and epithelialization), ulcer surroundings, and associated symptoms. Pain intensity was evaluated with visual analog scale (VAS). The results of the study demonstrated that the FREMS treatment accelerated ulcer healing, reduced pain, and demonstrated better efficacy compared to the control group ($P < .05$). The authors concluded that FREMS therapy was a safe and effective therapy for tissue repair and healing of chronic leg ulcers of various etiologies.
- A systematic review performed by Barnes and colleagues (2014) investigated the effectiveness of electrical stimulation on chronic ulcer healing and ulcer size reduction. The meta-analysis included 21 randomized controlled trials that compared any type of electrical stimulation with standard treatment and/or sham treatment in terms of impact on ulcer healing rates. The etiology of ulcers varied between trials with 11 studies examining pressure ulcers, three studies examining venous ulcers, two studies examining diabetic ulcers, one study examining arterial ulcers, and four studies examining ulcers of mixed etiology. The results of the meta-analysis demonstrated that electrical stimulation improved mean percentage change in ulcer size by 24.62% ($P < .00001$) in six trials ($n = 210$). Moreover, electrical stimulation

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decreased ulcer size by 2.42 cm2 (P < .00001) in six trials (n = 266). Thus, the authors concluded that electrical stimulation appeared to increase the rate of ulcer healing and may be superior to standard care for ulcer treatment.

- Houghton et al., (2010) conducted a randomized controlled trial to investigate whether electric stimulation therapy (EST) administered as part of a community-based, home care interdisciplinary wound care program accelerated healing of pressure ulcers in people with spinal cord injury (SCI). The study randomized 34 participants with SCI and stage 2 to stage 4 pressure ulcers to 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 and SWC). The primary outcome measures were wound healing measured by reduction in wound size and improvement in wound appearance at three months. The results of the study demonstrated that the percentage decrease in wound surface area (WSA) at the end of the intervention period was significantly greater in the EST-SWC group (mean ± SD, 70 ± 25%) than in the SWC group (36 ± 61%; P = .048). The proportion of stage 3, 4, or unstageable pressure ulcers improving by at least 50% WSA was significantly greater in the EST and SWC group than in the SWC group (P = .02). Wound appearance was improved in wounds treated with EST and SWC but not SWC alone. In summary, the authors concluded that EST can stimulate healing of pressure ulcers in individuals with SCI, and moreover, this treatment could be successfully incorporated as part of an interdisciplinary wound care program in the community.

Professional organizations/societies:

- A 2014 clinical practice guideline published by the Association for the Advancement of Wound Care (AAWC) on the management of venous ulcers Durable Medical Equipment V1.0.2024 and pressure ulcers included electrical stimulation as a treatment modality for venous ulcers and as an adjunctive intervention when pressure ulcers did not respond to the first line of treatment (Bolton et al., 2014).
- In 2017, the Wound, Ostomy and Continence Nurses Society published guidelines on the prevention and management of pressure ulcers. The guidelines stated that electrical stimulation can be considered as adjunctive treatment and rated the evidence as level A, indicating that there are two or more supporting randomized controlled trials (RCTs) of at least ten humans with pressure ulcers (at Level I or II), a meta-analysis of RCTs, or a Cochrane Systematic Review of RCTs.

Codes

Codes addressed in this guideline

The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for

management details. Prior authorization of a code listed in this table is not a guarantee fo payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's heath insurance policy.

HCPCS Code	Description
E0761	Non-thermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device
E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified

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