A separate copy of this form must accompany each policy submitted for review. Policies submitted without this form will not be considered for review.

<table>
<thead>
<tr>
<th>Plan: Aetna Better Health</th>
<th>Submission Date: 11/01/2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy Number: 0680</td>
<td>Effective Date: 10/10/2019</td>
</tr>
<tr>
<td>Policy Name: Electrical Stimulation for Chronic Ulcers</td>
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</tr>
</tbody>
</table>

Type of Submission – Check all that apply:

- ☐ New Policy
- ☒ Revised Policy*
- ☐ Annual Review – NoRevisions
- ☐ Statewide PDL

*All revisions to the policy must be highlighted using track changes throughout the document. Please provide any clarifying information for the policy below:

**CPB 0680 Electrical Stimulation for Chronic Ulcers**

This CPB has been revised to state that the following are considered experimental and investigational: (i) microcurrent as an adjunctive therapy to enhance chronic wound healing; and (ii) VeinoPlus device for the treatment of venous ulcers.

<table>
<thead>
<tr>
<th>Name of Authorized Individual (Please type or print):</th>
<th>Signature of Authorized Individual:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Bernard Lewin, M.D.</td>
<td>Bernard Lewin, M.D.</td>
</tr>
</tbody>
</table>
Electrical Stimulation for Chronic Ulcers

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.*

I. Aetna considers electrical stimulation (electrical current via electrodes placed directly on the skin in close proximity to the ulcer) medically necessary durable medical equipment (DME) for the management of the following types of chronic ulcers when it is used as adjunctive therapy after there are no measurable signs of healing for at least 30 days of treatment with conventional wound treatments.

A. Arterial ulcers; or
B. Diabetic ulcers; or
C. Stage III (defects extending into the muscle) or Stage IV (defects extending into the bone or the joint) pressure ulcers; or
D. Venous stasis ulcers.

Aetna considers electrical stimulation for chronic ulcers experimental and investigational when these criteria are not met.

**Note:** Conventional wound treatments include optimization of nutritional status, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, and necessary care to resolve any infection that may be present. Specific wound care based on type of wound...
includes frequent repositioning of a member with pressure ulcers (usually every 2 hours); off-loading of pressure and good glucose control for diabetic ulcers; establishment of adequate circulation for arterial ulcers and the use of a compression system for members with venous ulcers.

**Note:** A course of electrical stimulation therapy for chronic cutaneous ulcers would not typically be expected to exceed 60 minutes per day, or a total duration of more than 4 weeks. Courses of electrical stimulation therapy for chronic cutaneous ulcers exceeding 1 hour per day are not considered medically necessary, as prolonged treatments beyond 1 hour per day have not been proven to offer additional clinically significant benefits.

**Note:** Continued electrical stimulation is not considered medically necessary if measurable signs of healing have not been demonstrated within a 4-week treatment period. Measurable signs of improved healing include a decrease in wound size either in surface area or volume, decrease in amount of exudates and decrease in amount of necrotic tissue.

Aetna considers continued electrical stimulation not medically necessary once the wound demonstrates a 100 % epithelialized wound bed.

II. Aetna considers electrical stimulation for the treatment of chronic ulcers in the home setting not medically appropriate.

III. Aetna considers electrical stimulation for (i) the prevention of ulcers and pressure sores and (ii) the treatment of infected wounds experimental and investigational because its effectiveness for this indication has not been established.

IV. Aetna considers frequency rhythmic electrical modulation and wireless micro-current stimulation experimental and investigational for the treatment of chronic ulcers because their effectiveness for this indication has not been established.

V. Aetna considers combined use of modulated ultrasound and electric current stimulation for the treatment of diabetic foot ulcers experimental and investigational because the effectiveness of this approach has not been established.

VI. Aetna considers microcurrent as an adjunctive therapy to enhance chronic wound healing experimental and investigational because the effectiveness of this approach has not been established.
VII. Aetna considers the VeinoPlus device for the treatment of venous ulcers experimental and investigational because its effectiveness has not been established.

See also CPB 0175 - High-Frequency Pulsed Electromagnetic Stimulation (../100_199/0175.html) and CPB 0244 - Wound Care (../200_299/0244.html).

Background

It is known that living tissues possess electrical potentials that may play a role in the healing process. Early studies by Wolcott et al (1969) showed that ischemic ulcers healed significantly faster following electrostimulation. Their observations were supported by the findings of Gault and Gatens (1976), Carley and Wainapel (1985), Kloth and Feedar (1988), Mulder (1991), Griffin et al (1991), as well as Feedar et al (1991).

Cutaneous ulcerations can arise as a consequence of circulatory disturbances such as varicose veins and obliterator arterial disease (commonly associated with diabetics), severe injury from frostbite or burns, or complications in mobility impaired and bedridden patients. In particular, pressure (decubitus) ulcers are common among patients with spinal cord injury (SCI). Mawson et al (1988) noted that about 60% of SCI patients developed pressure ulcers within 30 days after their admittance to the hospital, while Richardson and Meyer (1981) reported a 41% incidence of pressure ulcers in SCI patients when they were first admitted to a rehabilitation facility. Such lesions are the primary cause of extended hospitalization, delayed rehabilitation, and hospital readmission for SCI patients.

For treatment of such lesions, electrostimulation has been demonstrated to be effective although the cellular and biochemical mechanisms for its beneficial effects are still unclear. From published studies, the duration of this type of electro-therapy was usually 1 hour per day lasting for about 4 weeks. There were no reports of adverse side effects resulting from electrostimulation. Additionally, the treated wounds needed less debridement, were without wound infections, and healed with stronger scar tissue when compared with untreated wounds (Carley and Wainapel, 1985).

In a multi-center study, Mulder (1991) compared the healing of open-skin wounds treated with electrical stimulation (ES) with the healing of similar wounds treated with sham stimulation. A total of 59 patients with 67 wounds were enrolled in the study but results included evaluations from 47 patients with 50 wounds. The wounds were classified as pressure ulcers, vascular
lesions, or surgical wounds. The size of wounds included for study was between 4 cm² and 100 cm². The 14-week study consisted of a 4-week phase, randomized, double-blinded parallel group comparing the effectiveness and tolerance of electrical and sham stimulation of open-skin wounds. Patients from either group whose wounds were not completely healed at the end of the first phase were allowed to cross-over to actual treatment (10 weeks of open phase). Patients were examined at least once-weekly during which wounds were measured and clinical assessment of wound appearance was performed. Wounds were treated twice-daily for 30 mins with electrical or sham stimulation. Wound healing was determined by the percentage decrease in initial wound size and by the clinical response to treatment.

After 4 weeks of treatment, treated wounds demonstrated a 56 % reduction in size, while sham-treated wounds showed a 33 % reduction in size. A good (25 to 74 % of original wound size) or excellent (less than 25 % of original wound size) response was reported for 92.3 % of wounds in the treatment group (n = 26) as compared with 54.1 % of wounds in the control group (n = 24). After 10 weeks of treatment with ES in the open phase, 96 % of wounds (n = 26) exhibited a good or excellent response. The author concluded that ES should be considered as an adjunct for the treatment of open wounds.

In another randomized, double-blinded and controlled study, Griffin et al (1991) examined the efficacy of high-voltage pulsed current (HVPC) for healing of pressure ulcerations in SCI patients. A total of 17 patients with pelvic ulcers were randomly assigned to a HVPC group (n = 8) or a placebo HVPC group (n = 9). Therapy was administered 1 hour a day for 20 consecutive days. An intensity of 200 V was employed and the stimulator frequency was set at 100 pulses per second (pps). Measurements of ulcer surface area were performed prior to, and at days 5, 10, 15 and 20 following treatment. It was found that lesions in the HVPC group exhibited significantly larger percentage of reductions from their pre-treatment size than those in the placebo group at day 5 (32 versus 14 %), day 15 (66 versus 44 %) and day 20 (80 versus 52 %). The authors concluded that high-voltage pulsed current, in combination with good nursing care, could expedite the healing of pelvic ulcers in SCI patients.

Feedar et al (1991) compared healing of chronic dermal ulcers treated with pulsed ES with healing of similar lesions treated with sham ES in a randomized, double-blinded, multi-center study. A total of 47 patients with 50 stage II, III and IV ulcers were randomly assigned to a treatment group (n = 26) or a control group (n = 24). Ulcers in the treatment group were given 30 mins pulsed ES twice-daily at a frequency of 128 pps and a peak amplitude of 29.2 mA if the ulcers contained necrotic tissue or any drainage that was not sero-sanguinous. This protocol was continued for 3 days after the wound was debrided or showed sero-sanguinous drainage. The polarity of the treatment electrode on the ulcer was then altered every 3 days until the wound achieved a stage II classification. The frequency was then lowered to 64 pps, and the
treatment electrode polarity was altered every day until the ulcer was healed. Wounds in the control group were managed with the same protocol, except they were given sham ES. After 4 weeks, ulcers in the treatment and control groups were 44 and 67% of their pre-treatment size, and the weekly healing rates were 14 and 8.25%, respectively. Furthermore, 14 of the ulcers in the control group were crossed over to the treatment group after the patients completed 4 weeks of sham ES. At that time, these lesions were about 89% of their original size and showed a weekly healing rate of 2.9%. In contrast, the same ulcers were 49% of their size at the time of cross-over and exhibited a weekly healing rate of approximately 13% after 4 weeks of active ES. These data indicated that pulsed ES was beneficial in treating stage II, III, and IV chronic dermal ulcers.

In a randomized, double-blind, sham-controlled study, Wood et al (1993) reported that 25 (58%) stage II and III pressure ulcers treated with pulsed low-intensity direct current healed in 8 weeks, whereas only 1 (3%) ulcer healed and most ulcers increased in size when they received sham ES. The Agency for Health Care Policy and Research's Clinical Practice Guideline on “Treatment of Pressure Ulcers” (Bergstrom et al, 1994) also recommended ES as an adjunctive therapy for the treatment of Stage III and IV pressure ulcers that do not respond to conventional therapy. Baker et al (1997) concluded that ES, given daily with a short pulsed, asymmetric biphasic waveform, was effective for enhancement of healing rates for patients with diabetes and open ulcers.

Vanoncini and colleagues (2010) examined the feasibility of the use of functional electrical stimulation (FES) applied to the lower back muscles for pressure sores prevention in paraplegia. The hypothesis under study is that FES induces a change in the pressure distribution on the contact area during sitting. Tests were conducted on a paraplegic subject (T5), sitting on a standard wheelchair and cushion. Trunk extensors (mainly the erector spinae) were stimulated using surface electrodes placed on the skin. A pressure mapping system was used to measure the pressure on the sitting surface in 4 situations: (i) no stimulation; (ii) stimulation on one side of the spine only; (iii) stimulation on both sides, at different levels; and (iv) stimulation at the same level on both sides, during pressure-relief manoeuvres. A session of prolonged stimulation was also conducted. The experimental results showed that the stimulation of the erector spinae on one side of the spine can induce a trunk rotation on the sagittal plane, which causes a change in the pressure distribution. A decrease of pressure on the side opposite to the stimulation was recorded. The phenomenon is intensified when different levels of stimulation are applied to the 2 sides, and such change can be sustained for a considerable time (around 5 mins). The stimulation did not induce changes during pressure-relief manoeuvres. The authors concluded that the stimulation of the trunk extensors can be a useful tool for pressure sores prevention.
prevention, and can potentially be used in a routine for pressure sores prevention based on periodical weight shifts.

Kim and associates (2010) examined if sensory (sub-motor-threshold) ES may provide a convenient preventive intervention. A double-blinded, repeated measures study design was used to test the hypothesis that repeated use of sensory surface ES improves tissue health status in individuals with motor paralysis. A total of 6 adult males with complete SCI were randomly assigned to treatment or control groups. The treatment group received the ES intervention, while the control group received a control sham intervention. Repeated tissue health assessments included transcutaneous oxygen tension (T\(\text{c}\)PO\(2\)), interface pressure mapping, and gluteal computed tomography (CT) studies. An initial increase in T\(\text{c}\)PO\(2\) following use of sub-threshold ES was observed but was not sustained at follow-up. No statistically significant changes before and after treatment were found in regional T\(\text{c}\)PO\(2\), gluteal muscle area or pressure distribution. Thus, sub-threshold ES does not appear to have any sustained effects on tissue health status indicative of reduced pressure ulcer risk for individuals with SCI. This implies that a contractile muscle response is critically important and further that sub-threshold ES is unlikely to prevent pressure ulcers. The authors concluded that further studies are needed to find solutions for preventing pressure ulcers in high-risk populations.

Santamato et al (2012) stated that frequency rhythmic electrical modulation system (FREMS) is an innovative type of transcutaneous electrotherapy used in a rehabilitation setting for the treatment of pain, especially in diabetic patients. In a randomized controlled trial (RCT), these researchers tested the hypothesis that FREMS is effective in the treatment of chronic and painful venous leg ulcers in 20 older patients. Group A \(n = 10\) received FREMS and topical treatment, whereas group B \(n = 10\) received topical treatment alone. Over a period of 3 consecutive weeks, 15 treatment sessions were done for each group. Wound healing and tissue repair were evaluated with the Visitrack digital planimetry system and photos. Pain was evaluated using the visual analog scale (VAS). The measurements were done at baseline and after 5, 10, and 15 days of treatment, with follow-up measurements after 15 and 30 days from the last treatment session. Group A showed a statistically significant decrease in ulcer area during the treatment and follow-up. The VAS score showed a statistically significant decrease after 5 and 10 days of treatment. Group B showed a statistically decrease in ulcer area after 5, 10, and 15 days of treatment with a reduction of VAS score only at 15 days of follow-up. At the end of the treatment, the comparison of the change in ulcer area and the change in VAS score of each group showed a statistically significant difference between groups, suggesting the therapeutic and analgesic effectiveness of FREMS in reducing pain and area of chronic venous leg ulcers in older adults. Moreover, the authors concluded that further investigation is needed to determine its reproducibility in larger case series or RCTs with longer follow-up periods.
Ramadhinara and Poulas (2013) noted that wireless micro-current stimulation (WMCS) is a new method in wound healing that may have advantages compared with conventional ES devices. Although ES has been widely known as an effective method to promote the wound-healing process in patients with type 2 diabetes mellitus, to the authors’ knowledge, there are still no data regarding the ability of WMCS to match the desired effect. In this article, the authors reported the results of 2 cases of diabetes-related wounds (1 acute and 1 chronic) that have been treated successfully using WMCS. The authors noted that neither patient reported discomfort during treatment; and the risk of infection was minimized because there was no direct contact from the device during the treatment course. These preliminary findings needed to be validated by well-designed studies.

Castana et al (2013) stated that high-voltage ES has been long proposed as a method of accelerating the wound healing process. Its beneficial effect has been successfully evaluated in the treatment of a number of chronic ulcers and burns. These investigators presented the implementation of a new wireless ES technique for the treatment of a complicated chronic ulcer of the lower limb. The device is transferring charges to the wound, without any contact with it, creating a micro-current that is able to generate the current of injury. The authors concluded that these results suggested that this easy-to-use method is an effective therapeutic option for chronic ulcers. More research is needed to ascertain the effectiveness of wireless ES in the treatment of chronic ulcers.

An UpToDate review on “Treatment of pressure ulcers” (Berlowitz, 2013) states that “Adjunctive therapies include electrical stimulation, in which a direct current is applied to the wound, has also resulted in enhanced healing in several small studies and a meta-analysis. The electric current is provided twice daily through a wound overlay and is believed to promote the migration and proliferation of fibroblasts. A systematic review of randomized trials of electromagnetic therapy, a distinct form of electrotherapy, found no evidence of benefit. Similarly, pulsed radiofrequency energy therapy and electromagnetic therapy have been proposed but evidence of benefit is limited”. Moreover, the review does not mention wireless ES as a therapeutic option for pressure ulcers.

Wirsing et al (2015) described their clinical experience with a new ES technique, the WMCS, for the treatment of chronic wounds. Wireless micro-current stimulation transfers the current to any surface wound from a distance, by using oxygen’s and nitrogen’s ability to exchange electrons. These researchers studied 47 patients with hard-to-heal wounds. Patients with venous, arterial and mixed leg ulcers were predominant; other etiologies such as diabetic foot lesions, pressure ulcers, vasculitis and pyoderma were also included. The WMCS protocol specified treatment of 2 or 3 sessions per week, for 45 to 60 minutes per session, with 1.5 μA current intensity. Standard wound care was applied to all patients, including compression bandages, if necessary.
Clear progress of wound healing, even after 2 weeks, was observed in all cases. The mean reduction of the wound surface after WMCS treatment was 95% in 8 weeks. Complete healing was achieved within 3 months for the majority of the cases. No clinical side effects were observed. The authors concluded that the WMCS technology significantly accelerated wound healing for patients with hard-to-heal wounds of different etiologies. They stated that this new therapy offers multiple advantages compared with the previous methods of ES, as it is contactless, free of pain and very easy to use. These preliminary findings need to be validated by well-designed studies.

The National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel, and Pan Pacific Pressure Injury Alliance’s clinical practice guideline on “Prevention of pressure ulcers” (2014) listed electrical stimulation of the muscles in spinal cord injured individuals as one of the emerging therapies for prevention of pressure ulcers.

Polak et al (2014) stated that a range of studies point to the effectiveness of ES in wound treatment, but the methodology of its application has not been determined to-date. These investigators provided a critical review of the results of clinical trials published by researchers using high-voltage pulsed current (HVPC) to treat chronic wounds. In describing the methodology of the trials, the article gave special attention to electric stimulus parameters, the frequency of procedures and total treatment duration. High-voltage pulsed current is a monophasic pulsed electric current that consists of double-peaked impulses (5 to 200 μs), at very high peak-current amplitude (2 to 2.5 A), and high voltage (up to 500 V), at a frequency of 1 to 125 pulses per second. High-voltage pulsed current can activate "skin battery" and cellular galvanotaxis, and improves blood flow and capillary density. The effectiveness of HVPC was evaluated in conservatively treated patients with diabetic foot, venous leg and pressure ulcers (PUs), and in some patients with surgically treated venous insufficiency. The authors concluded that the effectiveness of HVPC as one of several biophysical energies promoting venous leg ulcer (VLU) and PU healing has been confirmed. They stated that additional studies are needed to investigate its effect on the healing of other types of soft tissue defects. Other areas that require more research include the identification of the therapeutic effect of HVPC on infected wounds, the determination of the effectiveness of cathodal versus anodal stimulation, and the minimal daily/weekly duration of HVPC needed to ensure optimal promotion of wound healing.

Maillard (2015) noted that chronic wounds can take a long time to heal despite appropriate therapy based upon etiology and use of suitable dressings. The success of ES is based upon the existence within the skin of the endogenous currents involved in the wound healing process. Where skin continuity is broken by a wound, these electrical potentials are short-circuited, resulting in leakage of electrical current. Woundel therapy is the only such treatment currently available in France and is based on the use of continuous pulsed current that generates an
electrical field near the endogenous electrical fields. It utilizes a console to deliver the electrical impulses, a dressing electrode and a dispersion electrode. The electrode dressing is left on the wound for 3 days, and venous compression bandaging may be applied to the leg, taking care to leave the connector free. Negative polarity stimulates migration of fibroblasts, resulting in elimination of fibrin. Positive polarity causes keratinocyte migration, which in turn leads to epidermization. Electro-stimulation is a recognized utility in the healing of chronic wounds: it has been assigned a high-level recommendation in the European and American guidelines for the treatment of venous ulcers and bedsores with proof level of A. Furthermore, the analgesic effect of ES has been demonstrated in several studies. The author concluded that ES is already well-developed in France among wound specialists, but prospective studies are planned so that it may be used at patients’ homes.

Silver-Collagen Dressing and High-voltage, Pulsed-current Therapy

In a prospective, consecutive, case-series study, Zhou and colleagues (2016) examined the effect of the combined silver-collagen dressing and electrical stimulation for the treatment of chronic full-thickness wounds. All subjects were adults with wounds of at least 6 weeks’ duration. After obtaining informed consent, patient and wound characteristics were obtained, wounds were assessed and measured, and patients received 2 to 3 high-voltage, pulsed-current electric therapy (HVPC) treatments per week followed by application of the silver- and collagen-based dressing for a period of 2 weeks. Data were analyzed descriptively, and changes in wound size and volume from baseline were analyzed using Wilcoxon Signed Rank Test. The dressings were saturated with normal saline, used simultaneously during the 45-minute HVPC treatment, and left on top of the wound after treatment. The HVPC electro pads (stainless steel electrodes with a sponge interface) also were moistened with normal saline and the cathode placed on top of the wound. If the patient had more than 1 wound on the same leg, the anode was placed on the additional wound (otherwise over the intact skin nearby). Secondary dressings (e.g., foam and/ or gauze) were used as clinically appropriate, and a 4-layer compression wrap was used, if indicated, for patients with venous ulcers. A total of 10 patients (3 women and 7 men, age of 57.30 ± 9.70 years with 14 wounds of 273.10 ± 292.03 days’ duration before study) completed the study and were included in the final analyses. Average wound surface area decreased from 13.78 ± 21.35 cm(2) to 9.07 ± 16.81 cm(2) (42.52 % ± 34.16 % decrease, p = 0.002) and wound volume decreased from 3.39 ± 4.31 cm(3) to 1.28 ± 2.25 cm(3) (66.84 % ± 25.07 % decrease, p = 0.001); 1 patient was discharged with complete wound closure. No serious adverse events (AEs) were noted, but a diagnosis of osteomyelitis in 1 patient and increased pain in a patient with significant Reynaud's syndrome suggested clinicians should be cautious using HVPC in these instances. The authors concluded that combined intervention utilizing both HVPC and silver-collagen dressing was effective in the treatment of
chronic full thickness wounds in this patient population. Moreover, they stated that controlled clinical studies of longer duration are needed to further explore the safety, effectiveness, and effectiveness of this combinational therapy.

Combined Use of Modulated Ultrasound and Electric Current Stimulation for the Treatment of Diabetic Foot Ulcers

In a prospective, non-comparative, case-series study, O'Connor and colleagues (2017) evaluated the combined use of 2 therapies, ultrasound (US) and electro-stimulation (ES), in the treatment of diabetic foot ulcers (DFUs). This trial was undertaken in a podiatry-led diabetic foot clinic, in an acute hospital setting, in an urban location in Ireland. These researchers recruited patients with hard-to-heal DFUs who were treated twice-weekly with combined modulated US and ES. They recruited 7 patients with 8 chronic DFUs. A mean wound size reduction of 71% was achieved and there were no adverse reactions to the therapy. The authors concluded that the findings of this small case-series study indicated that combined modulated US and ES offered promise as an adjunct therapy for DFUs. Moreover, they stated that further large-scale trials are needed to verify these preliminary findings.

Microcurrent as an Adjunctive Therapy to Enhance Chronic Wound Healing

In a consecutive, case-series study, Nair (2018) examined the efficacy of microcurrent as an adjunctive therapy in enhancing healing in chronic wounds by reducing wound size and pain level. This investigator also evaluated the qualitative changes in these parameters: inflammatory symptoms, vasodilation, sleep quality, gait and frequency of bowel movement. Eligible patients with chronic wounds were enrolled between March and June 2016, from the Wound Care Unit, Hospital Kuala Lumpur in this trial. Standard wound care was performed with microcurrent as an adjunctive therapy. Each patient was treated with an anti-inflammatory frequency, followed by a vasodilation frequency, while having their wounds cleansed during each dressing change. Patients were loaned a home-microcurrent device to treat themselves 3 times daily using a tissue repair frequency for 4 weeks. A total of 100 patients with chronic wounds, such as diabetic foot ulcers, venous leg ulcers, and pressure ulcers, were recruited. During the 4-week treatment period, all patients had a reduction in wound size, with 16 having complete wound closure. All 89 of the 100 subjects who complained of pain, associated with their wound, experienced reduced pain scores, with 11 being pain-free at the end of the 4-week period. There was significant reduction (p < 0.001) in both mean pain score and mean wound area during the treatment period, as well as improvements in other parameters, such as reduction in inflammatory symptoms (leg swelling, foot stiffness), increased vasodilation (skin discoloration, leg heaviness, early morning erection, sensation), improvement in sleep quality, gait, and frequency of bowel movement. No AEs were reported. The authors concluded that the findings
of this study showed there was significant reduction in wound area and pain score during the treatment period. These researchers stated that the ease of use of microcurrent devices would advocate its use in enhancing wound healing. These preliminary findings need to be validated by well-designed studies.

The Veinoplus Device

Bogachev and associates (2015) analyzed the results of the electrical muscle stimulation (EMS) usage in patients with venous ulcers developed on top of a post-thrombotic syndrome (PTS). A total of 60 patients (60 legs) with active venous ulcer (C6EsAsdpPr according to CEAP classification) were divided into 2 groups. In addition to the background therapy consisting of a standardized compression with ULCER X and intake of micronized purified flavonoid fraction (MPFF 1,000 mg daily), all the patients in the main group underwent EMS with Veinoplus for at least 3 times a day. Follow-up examinations were performed on days 30, 60 and 90. These included pain severity assessment with 100-mm VAS, disease severity measurement with VCSS (Venous Clinical Severity Score) and ankle circumference above malleolus, as well as recording number of healed venous ulcers. At day 90 pain severity was reduced in both main and control groups. However, according to VAS pain reduction rates were significantly higher in patients of the main group (from 8.7 ± 0.6 to 1.9 ± 0.3 in the main group and 8.4 ± 0.6 to 3.9 ± 0.5 in the control group). At the end of the study, ankle circumference decreased from 270.9 ± 4.6 mm to 257.1 ± 4.2 mm in the main and from 269.7 ± 5.3 mm to 263.4 ± 5.2 in the control group. VCSS before treatment was 7.3 ± 0.6 in the main group and 6.8 ± 0.5 in the control group. By day 90 VCSS significantly decreased to 2.3 ± 0.4 and 4.6 ± 0.5 in the main and control groups, respectively. Healing rates were significantly higher in the main group. On day 90, the number of open venous ulcers in the main group was 3 times lower than in the control group (4 versus 12). The authors concluded that EMS demonstrated high efficacy and good tolerability and provided significant reduction in pain severity, VCSS score and ankle edema, as well as a 3-fold increase in the number of healed venous ulcers.

Benigni and colleagues (2018) noted that prolonged immobility in the sitting position in the elderly is known to produce venous stasis with leg edema and possible skin changes. Compression stockings are often applied for this clinical problem. There is few experienced nursing staff available to supervise the difficult task of stocking application. In a randomized, pilot study, these researchers evaluated other effective and simple devices that may be suitable alternatives. They reported the findings of 3 different devices to reduce leg edema, as measured by reduction in leg volume: an electro-stimulation device (Veinoplus), an adjustable compression Velcro wrap, and a short stretch bandage, each tested over a 2-hour period. In this trial of 38 patients, these investigators observed no difference in leg volume following Veinoplus. On the other hand, they observed a significant reduction in leg volume following use of the other 2
devices, more with the adjustable Velcro wrap compression (Circaid Juxtafit) than with the short stretch bandage (Rosidal K). Measurement of the interface pressures created by these 2 devices and also assessing the stiffness created by applying each device for 2 hours confirmed that pressure is more important than stiffness in the reduction of edema in these particular patients. The authors concluded that this pilot study should be added to the findings of previous published studies showing the efficacy in reducing leg edema of Velcro adjustable compression wrap and its ease of use.

CPT Codes / HCPCS Codes / ICD-10 Codes

*Information in the [brackets] below has been added for clarification purposes.* Codes requiring a 7th character are represented by "+":

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>CPT codes covered if selection criteria are met:</td>
<td></td>
</tr>
<tr>
<td>97014</td>
<td>Application of a modality to one or more areas; electrical stimulation (unattended)</td>
</tr>
<tr>
<td>97032</td>
<td>Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes</td>
</tr>
<tr>
<td>CPT codes not covered for indications listed in the CPB:</td>
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<tr>
<td>97035</td>
<td>Application of a modality to 1 or more areas; ultrasound, each 15 minutes [modulated ultrasound]</td>
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<tr>
<td>Other CPT codes related to the CPB:</td>
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<tr>
<td>11000</td>
<td>Debridement of extensive eczematous or infected skin; up to 10% of body surface</td>
</tr>
<tr>
<td>11001</td>
<td>each additional 10 % of the body surface (List separately in addition to code for primary procedure)</td>
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<tr>
<td>11042 - 11047</td>
<td>Debridement; subcutaneous tissue, muscle and/or fascia, bone</td>
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<tr>
<td>96574</td>
<td>Debridement of premalignant hyperkeratotic lesion(s) (ie, targeted curettage, abrasion) followed with photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s) provided by a physician or other qualified health care</td>
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<tr>
<td>97024</td>
<td>Application of a modality to one or more areas; diathermy (e.g., diathermy)</td>
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<td>Code</td>
<td>Code Description</td>
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<tr>
<td>97597</td>
<td>Debridement (eg, high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (eg, fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less</td>
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<tr>
<td>97598</td>
<td>each additional 20 sq cm, or part thereof (list separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>97602</td>
<td>Removal of devitalized tissue from wound(s), non-selective debridement, without anesthesia (e.g., wet-to-moist dressings, enzymatic, abrasion), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session</td>
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</table>

HCPCS codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
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<tbody>
<tr>
<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>
</tr>
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</table>

HCPCS codes not covered for indications listed in the CPB:

*Microcurrent therapy; VeinoPlus* - no specific code:

Other HCPCS codes related to the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>G0282</td>
<td>Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281</td>
</tr>
<tr>
<td>G0283</td>
<td>Electrical stimulation, (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care</td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>I74.2</td>
<td>Embolism and thrombosis of arteries of the upper extremities [arterial ulcers]</td>
</tr>
<tr>
<td>I74.3</td>
<td>Embolism and thrombosis of arteries of the lower extremities [arterial ulcers]</td>
</tr>
<tr>
<td>I74.5</td>
<td>Embolism and thrombosis of iliac artery [arterial ulcers]</td>
</tr>
<tr>
<td>I77.89</td>
<td>Other specified disorders of arteries and arterioles [arterial ulcers]</td>
</tr>
<tr>
<td>I83.001 - I83.029</td>
<td>Varicose veins of lower extremities with ulcer</td>
</tr>
<tr>
<td>I83.201 - I83.229</td>
<td>Varicose veins of lower extremities with ulcer and inflammation</td>
</tr>
<tr>
<td>Code</td>
<td>Code Description</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------</td>
</tr>
<tr>
<td>I87.2</td>
<td>Venous insufficiency (chronic) (peripheral) [venous stasis ulcers]</td>
</tr>
<tr>
<td>L89.000 - L89.95</td>
<td>Pressure ulcer [stage 3 or 4 only]</td>
</tr>
<tr>
<td>L97.101 - L97.929</td>
<td>Non-pressure chronic ulcer of lower limb</td>
</tr>
</tbody>
</table>

ICD-10 codes not covered for indications listing in the CPB (not all inclusive):

- S01.00x+ -
- S01.109+, S01.151+
- **S01.95x**,
- S21.001+ -
- S21.95x+, S31.000+
- **S31.839**,
- S41.001+ -
- S41.159+, S51.001+
- **S51.859, S61.001**
- **S61.559, S71.001**
- **S71.159**,
- S81.001+ -
- S81.859+, S91.001+
- **S91.359**

Open wound, skin

Frequency rhythmic electrical modulation and wireless micro-current stimulation:

No specific code

ICD-10 codes not covered for indications listing in the CPB (not all inclusive):

- L89.000 - L89.95 | Pressure ulcer |
- L97.101 - L97.929 | Non-pressure chronic ulcer of lower limb |

The above policy is based on the following references:

18. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Electrical stimulation or electromagnetic therapy as adjunctive treatments for chronic skin wounds. TEC Assessment Program. Chicago, IL: BCBSA; April 2005;20(2).


38. Berlowitz D. Treatment of pressure ulcers. UpToDate [serial online]. Waltham, MA: UpToDate; reviewed June 2013.


44. Kuffler DP. Improving the ability to eliminate wounds and pressure ulcers. Wound Repair Regen. 2015;23(3):312-317.


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Amendment to
Aetna Clinical Policy Bulletin Number: 0680
Electrical Stimulation for Chronic Ulcers

There are no amendments for Medicaid.