Kansas City

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Electrostimulation and Electromagnetic Therapy for Treating Wounds

Policy Number: 2.01.57
Origination: 8/2006
Last Review: 11/2018
Next Review: 11/2019

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for electrostimulation and electromagnetic therapy for the treatment of wounds. This is considered investigational.

Please note that this is a type of electrical stimulation that is considered a benefit exclusion in many health plan contracts.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

Electrical stimulation for the treatment of wounds, including but not limited to low-intensity direct current (LIDC), high-voltage pulsed current (HVPC), alternating current (AC), and transcutaneous electrical nerve stimulation (TENS)* for the treatment of wounds is considered **investigational**.

Electrical stimulation performed by the patient in the home setting for the treatment of wounds is considered **investigational**.

Electromagnetic therapy for the treatment of wounds is considered **investigational**.

Considerations

*TENS as a treatment of pain and other musculoskeletal conditions is considered in a separate policy.

Description of Procedure or Service

Populations	Interventions	Comparators	Outcomes
Individuals: ▪ With any wound	Interventions of interest are:	Comparators of interest are:	Relevant outcomes include: ▪ Symptoms

type (acute or nonhealing)	▪ Electrostimulation	▪ Standard wound care	▪ Change in disease status ▪ Morbid events ▪ Quality of Life ▪ Treatment-related morbidity
Individuals: ▪ With any wound type (acute or nonhealing)	Interventions of interest are: ▪ Electromagnetic therapy	Comparators of interest are: ▪ Standard wound care	Relevant outcomes include: ▪ Symptoms ▪ Change in disease status ▪ Morbid events ▪ Quality of Life ▪ Treatment-related morbidity

Electrical stimulation refers to the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. Electromagnetic therapy involves the application of electromagnetic fields rather than direct electrical current. Both are proposed as treatments for chronic wounds.

For individuals who have any wound type (acute or nonhealing) who receive electrostimulation, the evidence includes systematic reviews, randomized controlled trials (RCTs), and observational studies. Relevant outcomes are symptoms, change in health status, morbid events, quality of life, and treatment-related morbidity. Systematic reviews of RCTs on electrical stimulation have reported improvements in some outcomes, mainly intermediate outcomes such as decrease in wound size and/or the velocity of wound healing. There are few analyses on the more important clinical outcomes of complete healing and the time to complete healing, and many of the trials are of relatively low quality. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have any wound type (acute or nonhealing) who receive electromagnetic therapy, the evidence includes 2 systematic reviews of RCTs (one on pressure ulcers and the other on leg ulcers). Relevant outcomes are symptoms, change in health status, morbid events, quality of life, and treatment-related morbidity. The systematic reviews identified a few RCTs with small sample sizes that do not permit definitive conclusions. The evidence is insufficient to determine the effects of the technology on health outcomes.

Background

The normal wound healing process involves inflammatory, proliferative, and remodeling phases. When the healing process fails to progress properly and the wound persists for longer than 1 month, it may be described as a chronic wound. The types of chronic wounds most frequently addressed in studies of electrical stimulation for wound healing are 1) pressure ulcers, 2) venous ulcers, 3) arterial ulcers, and 4) diabetic ulcers.

Conventional or standard therapy for chronic wounds involves local wound care as well as systemic measures including debridement of necrotic tissues, wound cleansing, and dressing that promote a moist wound environment, antibiotics to

control infection, and optimizing nutritional supplementation. Non-weight bearing is another important component of wound management.

Since the 1950s, investigators have used electrical stimulation as a technique to promote wound healing, based on the theory that electrical stimulation may:

- Increase ATP concentration in the skin
- Increase DNA synthesis
- Attract epithelial cells and fibroblasts to wound sites
- Accelerate the recovery of damaged neural tissue
- Reduce edema
- Increase blood flow
- Inhibit pathogenesis.

Electrical stimulation refers to the application of electrical current through electrodes placed directly on the skin in close proximity to the wound. The types of electrical stimulation and devices can be categorized into 4 groups based on the type of current: 1) low intensity direct current (LIDC), 2) high voltage pulsed current (HVPC), 3) alternating current (AC), and 4) transcutaneous electrical nerve stimulation (TENS).

Electromagnetic therapy is a related but distinct form of treatment that involves the application of electromagnetic fields rather than direct electrical current.

Regulatory Status

No electrical stimulation or electromagnetic therapy devices have received approval from the U.S. Food and Drug Administration (FDA), specifically for the treatment of wound healing. A number of devices have been cleared for marketing for other indications. Use of these devices for wound healing is an off-label indication.

Rationale

This evidence review was created in July 2003 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through November 15, 2017.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more

intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

A 2005 TEC Assessment concluded that there was insufficient evidence from high-quality RCTs that electrostimulation and/or electromagnetic therapy are effective as standard adjunctive treatments for wound healing.[1] At the time, few RCTs were available, and they tended to have small sample sizes and poor methodologic quality. The following is a summary of the key literature.

ElectroStimulation

After the TEC Assessment, several RCTs and systematic reviews on electrostimulation for treating wounds have been published.[2-8] Two of the systematic reviews pooled study findings.

Systematic Reviews

The 2014 systematic review by Barnes et al included RCTs evaluating the comparative effectiveness of electrostimulation for chronic ulcers of any etiology and standard treatment and/or sham stimulation.[2] Twenty-one trials were selected; 14 used pulsed currents, 5 used alternating currents, and 2 used direct currents. Pressure ulcers were evaluated in 11 studies, venous ulcers in 3 studies, diabetic ulcers in 2 studies, arterial ulcers in 1 study, and ulcers of mixed etiology in the remaining 4 studies. Only 5 of the 21 trials were rated as "good" quality (ie, a score of 4 or 5 on the Jadad scale). Studies generally did not report the clinically important outcomes of percent completely healed or time to complete healing. Instead, they reported outcomes related to the decrease in wound size. Meta-analyses were performed on several of these secondary outcomes. A pooled analysis of 6 studies (n=201 patients) found that electrostimulation increased the mean percentage change in ulcer size by 24% to 62% compared with standard care and/or sham stimulation. The difference between groups was statistically significant ($p<0.001$), and heterogeneity among trials was not significant. Another pooled analysis of 6 RCTs (n=266 patients) found that electrostimulation resulted in a significantly greater reduction in mean absolute ulcer size compared with standard care and/or sham stimulation. The mean difference in size between groups was 2.42 cm^2 (95% confidence interval [CI], 1.66 to 3.17 cm^2; $p<0.001$) and there was significant heterogeneity. Reviewers conducted sensitivity analyses, and the significant benefit of electrostimulation on ulcer size remained when studies of pulsed current and direct current were analyzed separately. Limitations of the evidence base identified in the systematic review included few high-quality studies, variability in study designs, and lack of data on complete healing.

A 2016 systematic review by Lala et al addressed electrostimulation for treating pressure ulcers in individuals with spinal cord injury.[6] Fifteen studies met inclusion criteria; 6 were RCTs, 6 were prospective controlled trials, 2 were retrospective controlled trials, and 4 were case series. Several studies, published by the same research group and using the same populations, might have overlapped. Reviewers used a 10-point methodologic quality score and judged the overall quality of the controlled studies to be low (mean quality score, 5.3). A pooled analysis was conducted of data from 4 RCTs that reported healing rate. Sample sizes were small; 2 of the 4 RCTs included fewer than 20 patients. In the pooled analysis, pressure ulcer healing was significantly higher with electrostimulation than sham stimulation or usual care (relative risk [RR], 1.55; 95% CI, 1.12 to 2.15). Several other pooled analyses assessed outcomes related to wound size (of less clinical interest) and data from nonrandomized studies.

A 2017 meta-analysis by Khouri et al included 29 randomized trials (total N=1510 patients; total N=1753 ulcers) of individuals treated with electrostimulation, sham stimulation, or standardized wound care.[9] The primary finding was a highly heterogeneous overall standardized mean difference of 0.72 (95% CI, 0.48 to 1; I^2=78%). Modalities varied: in 18 studies, active electrostimulation was placed near the wound, and in 17 studies, electrostimulation was placed over the wound; additionally, types of waveform varied between studies (types included direct-, high-, or low-voltage current, and alternating current). Electrostimulation had the greatest efficacy when the active electrode was placed over the wound, and high-voltage pulsed current (HVPC) was used (standardized mean difference, 0.8; 95% CI, 0.38 to 1.21; I^2=79%). Other factors that may have affected the efficacy of electrostimulation were ulcer type, size, and duration (small, quick-healing pressure ulcers were favorable), although the association was not statistically significant (p=0.28). In subgroup analyses, reviewers found a greater sensitivity for wound size area than for other outcomes. Potential sources of heterogeneity were electrode polarity, ulcer etiology, and type of outcome. Reviewers noted that 52% of the studies had a high risk of bias, but concluded that the overall safety and efficacy of electrostimulation seem confirmed, given the current evidence.

Randomized Controlled Trials

Representative RCTs on electrostimulation for treating chronic wounds are described next (this includes the most recently published trials identified in systematic reviews).

In 2010, Houghton et al in Canada published a single-blind trial evaluating the effect of adding treatment with HVPC to a community-based standard wound care program.[4] The trial included 34 adults with spinal cord injuries and stage II to IV pressure ulcers of at least 3 months in duration. The trial excluded potential participants who were likely to have limited healing potential (eg, those with anemia or uncontrolled diabetes). Patients in the HVPC group or their caregivers were trained to administer the treatment and instructed to apply it for 8 hours per day (eg, overnight). (A compliance analysis found that HVPC treatment was actually used for a mean of 3 hours per day.) All randomized patients completed the 3-month follow-up. Two wounds, both in the standard care only group, were

unstageable. The primary efficacy outcome (the percentage decrease in wound care surface) was significantly greater in the group receiving HVPC (n=16) than in the standard care only group (n=18) (mean decrease, 70% vs 36%, respectively; p=0.048). By 3 months, all stage II wounds had healed (one in the HVPC group, four in the standard care only group). The number of the remaining wounds (stage III, IV, or unstageable) that were at least 50% smaller at 3 months was 12 (80%) of 15 in the HVPC group and 5 (36%) of 14 in the standard care only group; this difference was statistically significant (p=0.02). There was no statistically significant difference in the number of wounds completely healed at 3 months—six in the HVPC group and five in the standard care only group.

In 2012, Franek et al in Poland evaluated high-voltage electrical stimulation for treating lower-extremity pressure ulcers in an unblinded RCT.[3] Fifty-seven patients with stage II or III pressure ulcers were randomized to electrostimulation plus standard wound care or standard care only. The electrical stimulation intervention involved five 50-minute procedures per week until the wound was healed or until a maximum of 6 weeks. Fifty (88%) of 57 patients completed treatment. After 6 weeks, there were statistically significantly greater changes in the treatment group than in the control group on several outcomes. They included change in wound surface area (88.9% vs 44.4%, p<0.001) and change in the longest length of the wound (74.0% vs 36.1%, p<0.001), respectively. The rate of complete healing was not reported because trialists were unable to follow patients long enough for healing to occur.

In 2017, Polak et al conducted a prospective RCT in which 63 patients were randomized to cathodal or cathodal plus anodal electrostimulation by high-voltage monophasic pulsed current or sham stimulation.[10] All patients had pressure ulcers of 0.5 cm^2 or greater on the pelvic girdle, and most patients (n=49 [77.78%]) were immobile; also, regardless of the regimen administered, standard wound care was given to all patients. Of patients who received high-voltage monophasic pulsed current, 23 were given daily 50-minute treatments of cathodal electrostimulation 5 times per week for 6 weeks; a comparator group (n=20) was given cathodal stimulation for 1 week, then anodal stimulation for 5 weeks. No statistically significant differences in wound-related outcomes were observed between cathodal and cathodal-anodal groups, although outcomes in both groups were significantly superior to those for the group receiving sham stimulation. Decreases in wound size area of 82.34% and 70.77% for the cathodal and cathodal-anodal groups, respectively, were significantly larger than the decrease observed in the placebo group (40.53%). Similarly, the high-voltage monophasic pulsed current groups achieved a 50% decrease in wound size area faster (1.92 weeks and 2.60 weeks) than the sham group (10.60 weeks). During the 6 weeks of treatment, 47.83% of wounds treated with cathodal stimulation closed, as did 45% of those treated with cathodal-anodal stimulation. For the sham group, none of the patients achieved full wound closure at 6 weeks. These results would suggest that the active stimulation protocols were comparable in efficacy and superior to standard wound care. Limitations of the trial were that the authors did not confirm blinding rates or follow patients to complete wound closure, so the optimal treatment time was not determined.

Section Summary: Electrostimulation
The evidence on the use of electrostimulation to treat wounds includes 2 systematic reviews, a meta-analysis, and 3 RCTs. Many studies reported short-term outcomes such as wound healing rate or decrease in wound size; several of the trials found improvements for these outcomes. However, few studies evaluated complete healing or time to complete healing, two more clinically important outcomes. Systematic reviews were limited by the inclusion of studies with poor methodological quality and high heterogeneity.

Electromagnetic Therapy
Two Cochrane reviews have evaluated electromagnetic therapy for treating wounds: one addressed the treatment of pressure ulcers (last updated in 2012) and the other addressed leg ulcers (last updated in 2015).[11,12] Each review identified a few RCTs (2 and 3 studies, respectively) with small sample sizes. Consequently, these reviewers were unable to conduct robust pooled analyses of study findings. Both concluded that there is insufficient evidence that electromagnetic therapy is effective for treating chronic wounds.

Khooshideh et al (2017) reported on an RCT of 72 women treated with pulsed electromagnetic field (PEMF) therapy or sham PEMF following Cesarean section.[13] The primary outcome was a reduction of pain during recovery, which was assessed using visual analog scale (VAS) at regular intervals for 7 days following surgery. At each assessment, women treated with PEMF (n=36) reported significantly lower levels of pain than did their counterparts treated with sham (n=36). For example, 2 hours after surgery, PEMF patients had a mean VAS score of 53 compared with that of sham patients (VAS score, 63; p=0.01). Comparisons were similar between groups through the seventh day of follow-up, when the PEMF group reported a mean VAS score of 0.8 and the sham group reported a mean VAS score of 3 (p=0.01). The percentage of patients who reported severe pain (defined as VAS score, ≥75) 24 hours or less after surgery was lower in the PEMF group (36%) than in the sham group (72%; p=0.002). Secondary outcomes were wound healing and use of the pain medication available to each patient at discharge (diclofenac suppository 100 mg as needed); unlike other outcomes, wound healing was assessed 10 days after surgery, rather than 7. None of the patients in the PEMF group showed signs of wound exudate or edema, compared with 13% and 11% of sham patients who had exudate or edema, respectively (p=0.04). Patients in the PEMF group consistently used fewer suppositories to treat postoperative pain (mean, 1.7) than those treated with sham (mean, 3.7; p<0.001). Patients in both groups took an average of 3 to 4 days before they were able to resume normal activities, with no significant difference between groups (p=0.58), but listed no limitations to their study other than a change from 10 days of follow-up to 7.

Section Summary: Electromagnetic Therapy
The evidence on the use of electromagnetic therapy includes 2 systematic reviews of RCTs (one on pressure ulcers and the other on leg ulcers) and an RCT of electromagnetic treatment following Cesarean section. The reviews were limited by

the inclusion of small studies and a lack of robust pooled analyses. The RCT was focused primarily on postoperative pain, with wound healing being a secondary outcome that was assessed according to a previous protocol. The evidence on the use of electromagnetic therapy to treat wounds is inadequate to support drawing conclusion about efficacy.

Summary of Evidence

For individuals who have any wound type (acute or nonhealing) who receive electrostimulation, the evidence includes systematic reviews, a meta-analysis, and RCTs. Relevant outcomes are symptoms, change in health status, morbid events, quality of life, and treatment-related morbidity. Systematic reviews of RCTs on electrical stimulation have reported improvements in some outcomes, mainly intermediate outcomes such as a decrease in wound size and/or the velocity of wound healing. There are few analyses on the more important clinical outcomes of complete healing and the time to complete healing, and many of the trials are of relatively low quality. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have any wound type (acute or nonhealing) who receive electromagnetic therapy, the evidence includes 2 systematic reviews of RCTs (one on pressure ulcers and the other on leg ulcers) and an RCT of electromagnetic treatment following Cesarean section. Relevant outcomes are symptoms, change in health status, morbid events, quality of life, and treatment-related morbidity. The systematic reviews identified a few RCTs with small sample sizes that do not permit drawing definitive conclusions. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

American College of Physicians

In 2015, the American College of Physicians published guidelines on the treatment of pressure ulcers.[14] The guidelines recommended the electrostimulation be used as adjunctive treatment in patients with pressure ulcers. This was considered by the College to be a weak recommendation, based on moderate-quality evidence.

Association for the Advancement of Wound Care

In 2014, the Association for the Advancement of Wound Care published guidelines on the care of venous ulcers and pressure ulcers.[15] Guidelines for venous ulcer care included electrostimulation and electromagnetic stimulation as treatment modalities. Guidelines for pressure ulcer care include electrostimulation as adjunctive interventions when pressure ulcers do not respond to the first line of treatment.

Previously, in 2010, the Association published guidelines on the care of pressure ulcers.[16] Electrostimulation was included as a potential second-line intervention if first-line treatments did not result in wound healing.

Wound, Ostomy and Continence Nurses Society

In 2016, the Wound, Ostomy and Continence Nurses Society published guidelines on prevention and management of pressure ulcers.[17] The guidelines stated that electrostimulation can be considered as adjunctive treatment and rated the evidence as level A.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

National Medicare coverage of electrostimulation and electromagnetic stimulation is limited to chronic stage III or IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers.[18]

Effective 2004, Medicare's national coverage decision is as follows:

1. "ES and electromagnetic therapy will not be covered as an initial treatment modality.
2. Continued treatment with ES and electromagnetic therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.
3. Unsupervised use of ES or electromagnetic therapy for wound therapy will not be covered….

All other uses of ES and electromagnetic therapy not otherwise specified for the treatment of wounds remain at local Medicare Administrative Contractor discretion."

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in December 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

References

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Billing Coding/Physician Documentation Information

97014 Application of a modality to 1 or more areas; electrical stimulation (unattended)

97032 Application of a modality to one or more areas; electrical stimulation (manual), each 15 minutes

G0281 Electrical stimulation, (unattended), to one or more areas, for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care

G0282 Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281

G0295 Electromagnetic therapy, to one or more areas, for wound care other than described In G0329 or for other uses

G0329 Electromagnetic therapy, to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and

	venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapay plan of care
E0761	Nonthermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device
E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified

ICD-10 Codes

E08.621, E08.622, E09.621, E09.622, E10.621, E10.622, E11.621, E11.622, E13.621, E13.622	Various types of diabetes with skin complications (foot ulcer or other skin ulcer) code list
I83.001-I83.029; I83.201-I83.229	Varicose veins with ulcer code range
L00-L08.9	Infections of the skin code range (includes cellulitis – L03)
L89.00-L89.95	Pressure ulcer code range
L97.10-L97.929	Non-pressure chronic ulcer of skin code range
L98.41-L98.499	Non-pressure chronic ulcer of skin not otherwise classified code range
L99	Other disorders of skin and subcutaneous tissue in diseases classified elsewhere

The HCPCS code G0281 (unattended electrical stimulation) was specifically developed to distinguish between attended and unattended electrical stimulation. Attended electrical stimulation is identified by CPT code 97032. Although the description of this CPT code is nonspecific and could describe any type of electrical stimulation, electrical stimulation for wound healing would not require constant attendance, and thus the CPT code would not be applicable.

The Medicare policy notes that coverage for electrical stimulation is limited to supervised settings. Although the terminology is confusing, for Medicare policy, supervised is interpreted to mean that while a physician or other health professional is supervising the treatment, this person does not have to be in constant attendance. Therefore, to implement the Medicare policy, "supervised" essentially means "unattended" as described in the G code.

Additional Policy Key Words

N/A

Policy Implementation/Update Information

8/1/06 New policy. Considered investigational. Previously covered under the Miscellaneous Investigational Electrical Stimulation Devices as investigational.
8/1/07 No policy statement changes.
8/1/08 No policy statement changes.
8/1/09 No policy statement changes.
8/1/10 No policy statement changes.
8/1/11 Policy title changed to remove reference to "chronic." No policy statement changes.
8/1/12 No policy statement changes.
8/1/13 No policy statement changes.
8/1/14 The first policy statement was edited to clarify the intent.
9/1/15 No policy statement changes.
11/1/15 No policy statement changes.
11/1/16 No policy statement changes.
11/1/17 No policy statement changes.
11/1/18 No policy statement changes.