Name of Policy:
Electrostimulation and Electromagnetic Therapy for the Treatment of Chronic Wounds

Policy #: 143  Latest Review Date: September 2014
Category: Medicine  Policy Grade: A

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**
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, low-intensity direct current (LIDC), high-voltage pulsed current (HVPC), alternating current (AC), and 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.

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 one 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 pressure ulcers, venous ulcers, arterial ulcers, and 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 promotes 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 adenosine 5'-triphosphate (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 and inhibit pathogenesis.

**Policy:**

**Effective for dates of service on or after January 1, 2014:**
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), does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Electrical stimulation performed by the patient in the home setting does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Electromagnetic therapy for the treatment of wounds does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

**Effective for dates of service prior to January 1, 2014:**
Electrical stimulation using low intensity direct current (LIDC), high voltage pulsed current (HVPC), alternating current (AC), and transcutaneous electrical nerve stimulation (TENS) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage as a treatment of Stage
III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers when a 30-day trial of initial wound management has failed and when performed in a supervised setting.

**Electrical stimulation performed by the patient in the home setting does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage, and is considered **investigational.**

**Electromagnetic therapy for the treatment of wounds does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is **investigational.**

**Electrical stimulation for wound therapy for longer than a 30-day period does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when there is no evidence of wound healing and is considered **not medically necessary.**

**Electrical stimulation will be reviewed every 30 days for evidence of continued improvement.**

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

**Key Points:**
There are many published articles on wound care and the use of electrical stimulation for the treatment of chronic wounds. The summary of the most recent literature reviews are listed below.

The policy was originally based on a 2002 technology review performed by the Centers for Medicare and Medicaid Services. The initial policy was that electrostimulation may be considered medically necessary for the treatment of chronic ulcers and electromagnetic stimulation was considered investigational. The statement on electrical stimulation was changed to investigational following publication of a TEC Assessment in 2005. The TEC Assessment concluded that there was insufficient evidence from high-quality, randomized controlled trials (RCTs) that electrical stimulation and/or electromagnetic therapy are effective as standard adjunctive treatments for wound healing. At the time, few RCTs were available, and they tended to have small sample sizes and poor methodologic quality.

Literature updates focused on RCTs, especially larger high-quality trials, and systematic reviews of RCTs. Moreover, the review focused on the most clinically important outcome in evaluating treatments for wound healing, percent of patients who heal completely following a course of treatment. Time to complete healing is another important, objective outcome measure. Secondary outcomes that have some clinical relevance are decrease in the size of a wound, pain associated with a wound, and facilitation of surgical closure. Adverse outcomes with electrical stimulation
and electromagnetic therapy are expected to be minimal but may include discomfort and infection associated with the device.

**Electrical Stimulation**

Subsequent to the TEC Assessment, several systematic reviews of the evidence on electrical stimulation for treating wounds have been published. Only one of the systematic reviews pooled study findings. This study, published in 2014 by Barnes et al, included RCTs evaluating the effectiveness of electrical stimulation for chronic ulcers of any etiology compared with standard treatment and/or sham stimulation. Twenty-one trials were included in the review; 14 used pulsed currents, five used alternating currents, and two used direct currents. Types of ulcers examined were pressure ulcers in 11 studies, venous ulcers in three studies, diabetic ulcers in two studies, arterial ulcers in one study, and ulcers of mixed etiology in the remaining four studies. Only five of the 21 trials were rated as ‘good’ quality i.e., 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 tended to report outcomes related to the decrease in the size of wounds. Meta-analyses were performed on several of these secondary outcomes. A pooled analysis of 6 studies with a total of 201 patients found that electrical simulation 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 six RCTs with a total of 266 patients found that electrical stimulation 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 cm² (95% confidence interval, 1.66 to 3.17; p<0.001) and there was significant heterogeneity. The authors conducted sensitivity analyses and the significant benefit of electrical stimulation on ulcer size remained when studies on pulsed current and direct current were analyzed separately. Limitations of the evidence base identified in the systematic review include few high-quality studies, variability in study designs, and lack of data on complete healing.

Other systematic reviews were less comprehensive and did not conduct quantitative meta-analyses. A 2014 systematic review by Kawasaki et al addressed electrical stimulation only for pressure ulcers. The authors identified seven RCTs and two observational studies that included at least 15 patients. The authors found the greatest amount of support for high-voltage pulsed current (HVPC, as described in the Houghton et al 2010 and Franek et al 2012 studies next). Another 2014 systematic review, by Liu et al, identified six RCTs evaluating electrical stimulation for treating pressure ulcers in people with spinal cord injuries. Both reviews concluded that electrical simulation was effective for wound healing. Conclusions were largely based on secondary outcomes reported in studies such as change in wound size and interface pressure, rather than on complete healing.

Representative RCTs on electrical stimulation for treating chronic wounds are described next. This includes the most recently published trials identified in systematic reviews.

In 2005, Adunsky and colleagues published a randomized, double-blind, placebo-controlled trial to determine the benefits of adding direct current electrostimulation to conservative wound care for Stage III degree pressure sores of 30 days’ to 24 months’ duration. This multicenter trial of
63 patients found no significant differences in complete wound closure or time to complete wound closure between the treatment groups after eight consecutive weeks of electrostimulation. Nor were there any significant differences between groups after an additional follow-up of 12 weeks. While the authors reported an increase in absolute wound area reduction and speed of wound healing up until the 45th day of treatment in the electrostimulation group, this was not statistically significant and did not result in a greater rate of complete wound closure.

In 2010, Houghton and colleagues in Canada published a single-blind trial evaluating the effect of adding treatment with high-voltage pulsed current to a community-based standard wound care program. The trial included 34 adults with spinal cord injuries and Stage II to IV pressure ulcers of at least three months’ duration. The study excluded potential participants who were likely to have limited healing potential including those whose blood tests indicated anemia, uncontrolled diabetes, hyperthyroidism or protein deficiency. Also excluded were individuals whose wounds were deep or tunneling and thus required surgical closure, and those who had unstable medical conditions requiring hospitalization. Patients in the HVPC group or their caregivers were trained to administer the treatment and instructed to apply it for eight hours per day; e.g., overnight. (An analysis of compliance found that HVPC treatment was actually used for a mean of three hours per day). All randomized patients completed the three-month follow-up. Two wounds, both in the standard care only group, were unstageable. The primary outcome, percentage decrease in wound care surface, was significantly greater in the group receiving HVPC (n=16) than the standard care only group (n=18), mean decrease of 70% versus 36%, respectively (p=0.048). By three months, all of the Stage II wounds had healed (one in the HVPC group and 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 three months was 12 of 15 (80%) in the HVPC group and five of 14 (36%) in the standard care only group; this difference was statistically significant (p=0.02). There was not a statistically significant difference in the number of wounds that were completely healed at three months; six in the HVPC group and five in the standard care only group.

In 2012, Franek and colleagues in Poland evaluated high-voltage electrical stimulation for treating lower extremity pressure ulcers in an unblinded RCT. Fifty-seven patients with Stage II or III pressure ulcers were randomized to receive electrical stimulation in addition to 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 reaching a maximum of six weeks. A total of 50 of 57 patients (88%) completed treatment. After six weeks, there were statistically significantly greater changes in the treatment group compared to the control group on several outcomes. These included change in wound surface area (88.9% vs. 44.4%, p<0.0001) and change in the longest length of the wound (74.0% vs. 36.1%, p<0.0001). The rate of complete healing was not reported; the authors noted that they were unable to follow patients long enough for healing to occur.

**Electromagnetic Stimulation**

Two Cochrane reviews have evaluated electromagnetic stimulation for treating wounds; one addressed treatment of pressure ulcers (last updated in 2012) and the other addressed leg ulcers (last updated in 2013). Each review identified few RCTs (two and three studies, respectively) with small sample sizes. Consequently, the investigators were not able to conduct robust pooled
analyses of study findings. Both reviews concluded that there is insufficient evidence that electromagnetic therapy is effective for treating chronic wounds.

**Summary**
There is insufficient evidence from well-designed randomized controlled trials (RCTs) that electrical stimulation or electromagnetic stimulation improves health outcomes for wound care patients beyond that provided by standard treatment. Systematic reviews of RCTs on electrical stimulation have reported improvements in some intermediate outcomes, such as decrease in wound size and/or the velocity of wound healing. However, there is insufficient evidence on the more important clinical outcomes of complete healing and the time to complete healing. For electromagnetic therapy, there is a lack of high-quality RCTs. Therefore, these treatments are considered investigational for the treatment of wounds.

**Practice Guidelines and Position Statements**
In 2010, the Association for the Advancement of Wound Care (AAWC) published a guideline on care of pressure ulcers. Electrical stimulation was included as a potential second-line intervention if first-line treatments did not result in wound healing. The guideline did not mention electromagnetic therapy.

In 2010, the Wound, Ostomy, and Continence Nurses Society published a guideline on prevention and management of pressure ulcers. The guideline stated that electrical stimulation can be considered as adjunctive treatment and rates the evidence as level B. Electromagnetic therapy was not mentioned.

**U.S. Preventive Services Task Force Recommendations**
Use of electrical stimulation and electromagnetic therapy for wound healing is not a preventive service.

**Key Words:**
Electrical stimulation, electromagnetic therapy, chronic wounds, low intensity direct current (LIDC), high voltage pulsed current (HVPC), alternative current (AC), transcutaneous electrical nerve stimulation (TENS), pressure ulcers, venous ulcers, arterial ulcers, and diabetic ulcers.

**Approved by Governing Bodies:**
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.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational and will be reviewed for medical necessity
Pre-certification/Pre-determination requirements: Not applicable

Current Coding:
CPT codes:

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

HCPCS code:
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
G0281 Electrical stimulation, (unattended), to one or more areas, for chronic Stage III and Stage IV pressure ulcers, arterial 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 stimulation, to one or more areas
G0329 Electromagnetic therapy, to one or more areas for chronic stage III and stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care.

References:

8. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Electrical stimulation or electromagnetic therapy as adjunctive treatments for chronic skin wounds. TEC Assessments 2005; Volume 20, Tab 2.


Policy History:
Medical Policy Group, October 2003 (1)
Medical Policy Administration Committee, October 2003
Available for comment November 3-December 17, 2003
Medical Policy Group, October 2005 (1)
Medical Policy Group, October 2007 (1)
Medical Policy Group, June 2008 (1)
Medical Policy Group, June 2010 (1): No policy changes
Medical Policy Group, October 2010 (1): No policy changes, Key Points updated.
Medical Policy Group, November 2010 No policy changes, References updated.
Medical Policy Group, October 2011 (1): Update to Key Points and References; no change to policy statement
Medical Policy Group, January 2013 (1): 2012 Update to Key Points and References; no change to policy statement
Medical Policy Panel, October 2013
Medical Policy Group, October 2013 (1): Update to Description, Policy, Key Points and References with change in coverage criteria related to electrical stimulation for wounds, now considered investigational, effective 01/01/2014; electromagnetic stimulation remains investigational

Medical Policy Administration Committee, November 2013
Available for comment November 8 through December 22, 2013

Medical Policy Panel, September 2014
Medical Policy Group, September 2014 (1) Update to Key Points and References; no change to policy statement

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.