



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

## Electrostimulation and Electromagnetic Therapy for Treating Wounds

**Policy #** 00030

**Original Effective Date:** 04/29/2002

**Current Effective Date:** 07/16/2014

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Transcutaneous electrical nerve stimulation as a treatment of pain and other musculoskeletal conditions is considered in medical policy 00142, Electrical Nerve Stimulation Devices.*

### **Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers 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), to be **investigational**.\*

Based on review of available data, the Company considers electrical stimulation performed by the patient in the home setting for the treatment of wounds to be **investigational**.\*

Based on review of available data, the Company considers electromagnetic therapy for the treatment of wounds to be **investigational**.\*

### **Background/Overview**

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.

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 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 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

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- 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 four groups based on the type of current: 1) LIDC, 2) HVPC, 3) AC and 4) TENS. Electromagnetic therapy is a related but distinct form of treatment that involves the application of electromagnetic fields rather than direct electrical current.

### **FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

No electrical stimulation or electromagnetic therapy devices have received approval from the 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.

Centers for Medicare and Medicaid Services (CMS)

National Medicare Coverage of electrical stimulation and electromagnetic stimulation is limited to chronic stage III or stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers.

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

1. Electrical stimulation and electromagnetic therapy will not be covered as an initial treatment modality;
2. Continued treatment with electrical stimulation 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 electrical stimulation or electromagnetic therapy is not covered;
4. All other uses of electrical stimulation and electromagnetic therapy for the treatment of wounds remain at the discretion of local contractors.

### **Rationale/Source**

In February 2005, a TEC Assessment on electrostimulation and electromagnetic therapy for the treatment of chronic wounds was conducted. The following summarizes the conclusions of the TEC Assessment:

- The most clinically important outcome in evaluating treatments for wound healing is the 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.
- The evidence is not sufficient to permit conclusions on the efficacy of electrical stimulation and electromagnetic therapy as adjunctive treatments for wound healing. For studies of wound healing, high-quality randomized, controlled trials (RCTs) are essential to determining the efficacy of an intervention independent of the many confounding factors and the variable natural history of the disorder. The body of evidence for electrical stimulation and electromagnetic therapy

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consisted of numerous small, relatively poor-quality RCTs (N=10 for electrical stimulation; N=5 for electromagnetic therapy) that compare active treatment with a placebo sham device.

- Although results suggest that electrical stimulation and electromagnetic therapy may promote wound healing or some aspect of wound healing, considerable uncertainty remains as to whether these modalities lead to clinically significant health outcome benefits, given the relatively poor quality of the available evidence. Larger RCTs are needed that focus on one type of wound, demonstrate baseline comparability on important confounders, and report the outcome of complete healing.

Based on the conclusions of the February 2005 TEC Assessment, the policy statement regarding electrostimulation of wounds was changed from may be considered medically necessary to investigational. Previously, consistent with conclusions of a 2002 technology review performed by the CMS, the policy had stated that electrostimulation may be considered medically necessary for the treatment of chronic ulcers. The policy on electromagnetic therapy of wounds has remained investigational.

Subsequent to the TEC Assessment, several systematic reviews on treatments for wounds have been published that address electrostimulation and/or electromagnetic stimulation for treating wounds. In 2012, Game and colleagues reviewed studies on interventions to enhance healing of diabetic foot ulcers and stated that they did not find sufficient evidence that electrical stimulation was clinically effective for treating foot ulcers. Moreover, 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 (2 and 3 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.

Representative RCTs on electrostimulation or electromagnetic stimulation for treating chronic wounds are described below.

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 8 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 HVPC 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 3 months' duration. The study excluded potential participants who were likely to have limited healing potential e.g., those with anemia or uncontrolled diabetes. Patients in the HVPC group or their caregivers were trained to administer the



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treatment and instructed to apply it for 8 hours per day e.g., overnight. (An analysis of compliance 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, 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 3 months, all of the stage II wounds had healed (1 in the HVPC group and 4 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 of 15 (80%) in the HVPC group and 5 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 3 months, 6 in the HVPC group and 5 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 6 weeks. A total of 50 of 57 patients (88%) completed treatment. After 6 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.

One small RCT on electromagnetic therapy, published in 2009, was identified. The study was conducted in India and included only 12 patients. Patients were inpatients with neurologic disorders and stage 3 or 4 pressure ulcers. Six patients were assigned to active treatment, and the other 6 were assigned to a sham intervention. After 6 months of follow-up, there was no significant difference between groups in the degree of wound healing. The sample size was too small to allow a meaningful comparison of the proportion of patients whose wounds had healed completely.

### Summary

There is insufficient evidence from well-designed RCTs that electrostimulation or electromagnetic stimulation improves health outcomes for wound care patients beyond that provided by standard treatment. Some small RCTs on electrostimulation have reported improvements in some intermediate outcomes, such as decrease in wound size and/or the velocity of wound healing. However, these studies have not demonstrated consistent improvements 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.

### References

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### Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	64550
HCPCS	C1816, C1883, G0281, G0282, G0283, G0295, G0329, E0761, E0769
ICD-9 Diagnosis	All relative diagnoses
ICD-9 Procedure	No codes

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### **Policy History**

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04/18/2002	Medical Policy Committee review
04/29/2002	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy.
08/03/2004	Medical Director review
08/17/2004	Medical Policy Committee review. Format revision. Policy change, eligible for coverage for identified uses.
08/30/2004	Managed Care Advisory Council approval
07/14/2005	Medical Director review
07/19/2005	Medical Policy Committee review. Coverage changed from "eligible" to investigational.
08/24/2005	Managed Care Advisory Council approval
07/07/2006	Format revision including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
05/02/2007	Medical Director review
05/23/2007	Medical Policy Committee approval. Policy updated with literature review. Policy statement unchanged.
05/07/2009	Medical Director review
05/20/2009	Medical Policy Committee approval. Title changed from "Electrostimulation and Electromagnetic Stimulation as Treatment of Chronic Wounds" to "Electrostimulation and Electromagnetic Stimulation for the Treatment of Chronic Wounds". Policy updated with literature review. Policy statement unchanged.
06/03/2010	Medical Policy Committee review
06/16/2010	Medical Policy Implementation Committee approval.
05/05/2011	Medical Policy Committee review
05/18/2011	Medical Policy Implementation Committee approval. The word "Chronic" was deleted from the title.
05/03/2012	Medical Policy Committee review
05/16/2012	Medical Policy Implementation Committee approval. No change to coverage.
06/27/2013	Medical Policy Committee review and approval
07/17/2013	Medical Policy Implementation Committee review and approval. Coverage eligibility unchanged.
07/10/2014	Medical Policy Committee review and approval
07/16/2014	Medical Policy Implementation Committee review and approval. First investigational statement clarified.

Next Scheduled Review Date: 07/2015

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

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3. Reference to federal regulations.

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