



# Louisiana

## Electrostimulation and Electromagnetic Therapy for Treating Wounds

**Policy #** 00030

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

**Current Effective Date:** 12/20/2017

*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**

Electrostimulation (aka 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

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Electrostimulation and Electromagnetic Therapy for Treating Wounds

Policy # 00030

Original Effective Date: 04/29/2002

Current Effective Date: 12/20/2017

- 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 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**

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 wound size and wound-associated pain, as well as 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.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Electrostimulation and Electromagnetic Therapy for Treating Wounds

Policy # 00030

Original Effective Date: 04/29/2002

Current Effective Date: 12/20/2017

A 2005 TEC Assessment concluded that there was insufficient evidence from high-quality 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.

### Electrical Stimulation

Subsequent to the TEC Assessment, several systematic reviews of the evidence on electrical stimulation for treating wounds have been published. Two of the systematic reviews pooled study findings.

### Systematic Reviews

A systematic review 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, 5 used alternating currents, and 2 used direct currents. Types of ulcers examined were pressure ulcers 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 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 stimulation 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 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 cm<sup>2</sup> (95% confidence interval [CI], 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.

A 2016 systematic review by Lala et al addressed electrical stimulation for treating pressure ulcers in individuals with spinal cord injury. A total of 15 studies met the inclusion criteria; 6 were RCTs, 6 were prospective controlled trials, 2 were retrospective controlled trials and 4 were case series. Several studies were published by the same research group and populations may have overlapped. The investigators used a 10-point methodological 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 electrical stimulation than sham stimulation or usual care (risk ratio [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 were of data from nonrandomized studies.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Electrostimulation and Electromagnetic Therapy for Treating Wounds

Policy # 00030

Original Effective Date: 04/29/2002

Current Effective Date: 12/20/2017

### Randomized Controlled Trials

Representative RCTs on electrical stimulation 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 high-voltage pulsed current (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-month duration. The study 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. (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, 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.

### Electromagnetic Therapy

Two Cochrane reviews have evaluated electromagnetic stimulation for treating wounds; 1 addressed treatment of pressure ulcers (last updated in 2012) and the other addressed leg ulcers (last updated in 2015).<sup>9,10</sup> 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.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Electrostimulation and Electromagnetic Therapy for Treating Wounds

Policy # 00030

Original Effective Date: 04/29/2002

Current Effective Date: 12/20/2017

### Summary of Evidence

For individuals who have any wound type (acute or nonhealing) who receive electrostimulation, the evidence includes systematic reviews, 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.

### References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual. "Electrostimulation and Electromagnetic Therapy for Treating Wounds", 2.01.57, 09:2017.
2. 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.
3. Barnes R, Shahin Y, Gohil R, et al. Electrical stimulation vs. standard care for chronic ulcer healing: a systematic review and meta-analysis of randomised controlled trials. *Eur J Clin Invest*. Apr 2014;44(4):429-440. PMID 24456185
4. Franek A, Kostur R, Polak A, et al. Using high-voltage electrical stimulation in the treatment of recalcitrant pressure ulcers: results of a randomized, controlled clinical study. *Ostomy Wound Manage*. Mar 2012;58(3):30-44. PMID 22391955
5. Houghton PE, Campbell KE, Fraser CH, et al. Electrical stimulation therapy increases rate of healing of pressure ulcers in community-dwelling people with spinal cord injury. *Arch Phys Med Rehabil*. 2010;91(5):669-678.
6. Kawasaki L, Mushahwar VK, Ho C, et al. The mechanisms and evidence of efficacy of electrical stimulation for healing of pressure ulcer: a systematic review. *Wound Repair Regen*. Mar-Apr 2014;22(2):161-173. PMID 24372691
7. Lala D, Spaulding SJ, Burke SM, et al. Electrical stimulation therapy for the treatment of pressure ulcers in individuals with spinal cord injury: a systematic review and meta-analysis. *Int Wound J*. Apr 13 2015. PMID 25869151
8. Liu LQ, Moody J, Traynor M, et al. A systematic review of electrical stimulation for pressure ulcer prevention and treatment in people with spinal cord injuries. *J Spinal Cord Med*. Jun 26 2014. PMID 24969965
9. Thakral G, La Fontaine J, Kim P, et al. Treatment options for venous leg ulcers: effectiveness of vascular surgery, bioengineered tissue, and electrical stimulation. *Adv Skin Wound Care*. Apr 2015;28(4):164-172. PMID 25775200
10. Aziz Z, Flemming K. Electromagnetic therapy for treating pressure ulcers. *Cochrane Database Syst Rev* 2012; 12:CD002930.
11. Aziz Z, Cullum N, Flemming K. Electromagnetic therapy for treating venous leg ulcers. *Cochrane Database Syst Rev* 2013; 2:CD002933.
12. Qaseem A, Humphrey LL, Forcica MA, et al. Treatment of pressure ulcers: a clinical practice guideline from the American College of Physicians. *Ann Intern Med*. Mar 3 2015;162(5):370-379. PMID 25732279
13. Association for the Advancement of Wound Care (AAWC). Association for the Advancement of Wound Care guideline of pressure ulcer guidelines. Available online at: [www.guideline.gov](http://www.guideline.gov). Last accessed July 9, 2015.
14. Wound, Ostomy and Continence Nurses Society (WOCN). Guideline for prevention and management of pressure ulcers. <http://www.guideline.gov/content.aspx?id=23868>. Accessed July 9, 2015.
15. CMS Manual System. Pub. 100-43 Medicare National Coverage Determinations. 2004. Available online at: [www.cms.hhs.gov](http://www.cms.hhs.gov). Last accessed July 9, 2015.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Electrostimulation and Electromagnetic Therapy for Treating Wounds

Policy # 00030

Original Effective Date: 04/29/2002

Current Effective Date: 12/20/2017

### **Policy History**

Original Effective Date: 04/29/2002

Current Effective Date: 12/20/2017

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.

08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.

10/29/2015 Medical Policy Committee review and approval

11/16/2015 Medical Policy Implementation Committee review and approval. Coverage eligibility unchanged.

12/01/2016 Medical Policy Committee review and approval

12/21/2016 Medical Policy Implementation Committee review and approval. Coverage eligibility unchanged.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

12/07/2017 Medical Policy Committee review and approval

12/20/2017 Medical Policy Implementation Committee review and approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 12/2018

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



# Louisiana

## Electrostimulation and Electromagnetic Therapy for Treating Wounds

Policy # 00030

Original Effective Date: 04/29/2002

Current Effective Date: 12/20/2017

### **Coding**

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT)<sup>‡</sup>, copyright 2016 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

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, E0761, E0769, G0281, G0282, G0295, G0329
ICD-10 Diagnosis	All related diagnoses

\*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 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
  - 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

©2017 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.