



# Louisiana

## **Electrostimulation and Electromagnetic Therapy for Treating Wounds**

**Policy #** 00030

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

**Current Effective Date:** 06/08/2020

*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.*

*Note: 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 electromagnetic therapy for the treatment of wounds to be **investigational**.\*

### **Background/Overview**

#### **Standard Treatment**

Conventional or standard therapy for chronic wounds involves local wound care, as well as systemic measures including débridement of necrotic tissues, wound cleansing, and dressing that promotes a moist wound environment, antibiotics to control infection, and optimizing nutritional supplementation. Avoidance of weight-bearing is another important component of wound management.

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### **Electrostimulation**

Since the 1950s, investigators have used electrostimulation to promote wound healing, based on the theory that electrostimulation may:

- Increase adenosine 5'-triphosphate 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.

Electrostimulation refers to the application of electrical current through electrodes placed directly on the skin near the wound. The types of electrostimulation and devices can be categorized into groups based on the type of current. This includes low-intensity direct current, high-voltage pulsed current, alternating current, and transcutaneous electrical nerve stimulation.

### **Electromagnetic Therapy**

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 electrostimulation 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 off-label.

## **Rationale/Source**

Electrostimulation (electrical stimulation) refers to the application of electrical current through electrodes placed directly on the skin. Electromagnetic therapy involves the application of electromagnetic fields, rather than direct electrical current. Both are proposed as treatments for wounds, generally chronic wounds.

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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 speed of wound healing. There are few analyses of the more important clinical outcomes of complete healing and the time to complete healing, and many of the trials are 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. [[Qaseem A, Humphrey LL, Forciea MA, et al. Treatment....;162\(5\):370-379. PMID 25732279](#)]. 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. 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.

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Previously, the Association (2010) published guidelines on the care of pressure ulcers. 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 the prevention and management of pressure ulcers. 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.

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](http://ClinicalTrials.gov) in November 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

## **References**

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Electrostimulation and Electromagnetic Therapy for Treating Wounds", 2.01.57, February 2020.

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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                                                                      |

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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

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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.

12/06/2018 Medical Policy Committee review and approval

12/19/2018 Medical Policy Implementation Committee review and approval. Coverage eligibility unchanged.

01/01/2019 Coding update

12/05/2019 Medical Policy Committee review

12/11/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

05/07/2020 Medical Policy Committee review

05/13/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 05/2021

### **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®)‡, copyright 2019 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.*

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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	No codes
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. Food and Drug Administration (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
  3. Reference to federal regulations.

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**\*\*Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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