

Policy # 00030

Original Effective Date: 04/29/2002 Current Effective Date: 06/01/2025

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: Noncontact Ultrasound Treatment for Wounds is addressed separately in medical policy 00808.

Note: Vacuum-Assisted Closure of Chronic Wounds (Negative Pressure Wound Therapy) is addressed separately in medical policy 00132.

Note: Electrical Nerve Stimulation Devices is addressed separately in medical policy 00142.

# **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 individuals 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**

#### **Standard Treatment**

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. 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 U.S. Food and Drug Administration 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

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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.

#### **Summary of Evidence**

For individuals who have any wound type (acute or nonhealing) who receive electrostimulation, the evidence includes systematic reviews and randomized controlled trials (RCTs). Relevant outcomes

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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 that the technology results in an improvement in the net health outcome.

For individuals who have any wound type (acute or nonhealing) who receive electromagnetic therapy, the evidence includes 2 systematic reviews of RCTs (1 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 that the technology results in an improvement in the net health outcome.

# **Supplemental Information**

#### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

#### **American College of Physicians**

In 2015, the American College of Physicians published guidelines on the treatment of pressure ulcers. The guidelines recommended that electrostimulation be used as adjunctive treatment in individuals with pressure ulcers. This was considered by the College to be a weak recommendation, based on moderate-quality evidence. This guideline is listed as "inactive" on the ACP website.

#### **Association for the Advancement of Wound Care**

In 2014, the Association for the Advancement of Wound Care (AAWC) 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.

Previously, the AAWC (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.

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#### 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.

In 2024, the Wound, Ostomy and Continence Nurses Society published guidelines on the management of wounds in patients with lower extremity arterial disease. They recommend electrotherapy/electrostimulation as an adjunct to increase perfusion and walking capacity, but the level of evidence was rated as B (at least 1 RCT or 2 nonrandomized trials) and the quality of evidence as low.

#### **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:

- "ES and electromagnetic therapy will not be covered as an initial treatment modality.
- 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.
- 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 <u>ClinicalTrials.gov</u> in November 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

### **References**

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# **Policy History**

05/16/2012

Policy History		
Original Effecti	ve Date: 04/29/2002	
Current Effective	ve Date: 06/01/2025	
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	

Medical Policy Implementation Committee approval. No change to coverage.

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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.
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.
05/06/2021	Medical Policy Committee review
05/12/2021	Medical Policy Implementation Committee approval. Coverage eligibility
05/05/2022	unchanged.
05/05/2022	Medical Policy Committee review
05/11/2022	Medical Policy Implementation Committee approval. Coverage eligibility
0.5 /0.4 /0.000	unchanged.
05/04/2023	Medical Policy Committee review
05/10/2023	Medical Policy Implementation Committee approval. Coverage eligibility
0.5.100.1000.4	unchanged.
05/02/2024	Medical Policy Committee review
05/08/2024	Medical Policy Implementation Committee approval. Coverage eligibility
05/01/2025	unchanged.
05/01/2025	Medical Policy Committee review

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05/13/2025 Medical Policy Implementation Committee approval. Coverage eligibility

unchanged.

Next Scheduled Review Date: 05/2026

# **Coding**

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology ( $CPT^{\circledast}$ )<sup>‡</sup>, copyright 2024 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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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	No codes
HCPCS	E0761, E0769, G0281, G0282, G0295, G0329 Delete codes effective 06/01/2024: C1816, C1883
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

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- 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 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:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**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.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.