Electrostimulation and Electromagnetic Therapy for Treating Wounds

Policy # 00030
Original Effective Date: 04/29/2002
Current Effective Date: 06/10/2024

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.

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.

Electrostimulation

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

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- 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 federal 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

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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 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

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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.

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:

- "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….

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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 in November 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

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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

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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 unchanged.
05/05/2022	Medical Policy Committee review
05/11/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/04/2023	Medical Policy Committee review

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05/10/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/02/2024	Medical Policy Committee review
05/08/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 05/2025

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	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
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.

**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

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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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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.

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