Policy Number	MED201.027
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Electrostimulation and Electromagnetic Therapy for Treating Wounds

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Related Policies (if applicable)
MED201.026: Surface Electrical Stimulation

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Electrical stimulation for the treatment of wounds, including but not limited to, low-intensity direct current, high-voltage pulsed current, alternating current, and transcutaneous electrical nerve stimulation, **is considered experimental, investigational and/or unproven.**

Electrical stimulation performed by individuals in the home setting for the treatment of wounds **is considered experimental, investigational and/or unproven.**

Electromagnetic therapy for the treatment of wounds **is considered experimental, investigational and/or unproven.**

Policy Guidelines

Diapulse® is one example of an electromagnetic therapy device; see MED201.026 for descriptions and more examples of electrical stimulation devices.

Description

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.

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:

- 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.

Regulatory Status

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

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Electrostimulation

Clinical Context and Therapy Purpose

The purpose of electrostimulation is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with any wound type (acute or nonhealing).

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with any wound type (acute or nonhealing).

Interventions

The therapy being considered is electrostimulation.

Comparators

Comparators of interest include standard wound care.

Outcomes

The general outcomes of interest are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity.

Follow-up over months is of interest for electrostimulation to monitor relevant outcomes.

Study Selection Criteria

Methodologically credible studies for indications within this review were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Several RCTs and systematic reviews on electrostimulation for treating wounds have been published. (1-8)

Systematic Reviews

In a meta-analysis specific to patients with diabetes-related ulcers, Zheng et al. (2022) identified 10 trials (N=352) comparing electrostimulation to standard of care or placebo. (8) Electrostimulation improved ulcer area reduction and healing rates; however, 4 studies were considered at high risk of bias, and there was high heterogeneity limiting applicability of these findings. Individual trial sample sizes were quite small, and additional properly designed RCTs are necessary to establish electrostimulation efficacy in patients with diabetes-related ulcers.

Arora et al. (2020) performed a Cochrane review comparing electrical stimulation plus standard care to sham/no electrical stimulation plus standard care for the management of pressure ulcers. (9) The review included 20 RCTs with a total of 913 patients (mean age range: 26 to 83 years) with pressure ulcers ranging from a mean of 4 days to more than 12 months. Fifty percent of the included studies were at risk of performance and detection bias; 25% were at risk of attrition and selective reporting bias. The Grading of Recommendations, Assessment, Development, and Education (GRADE) assessment of the certainty of evidence for outcomes was moderate to very low. Overall, the authors concluded that electrical stimulation probably increased the proportion of pressure ulcers healed and the rate of healing (moderate certainty evidence), but the effect on time to complete healing was uncertain compared to standard care (very low certainty evidence). Whether electrical stimulation reduces pressure ulcer surface area was also uncertain. The authors stated that current evidence is insufficient to support the widespread use of electrical stimulation for pressure ulcer management in clinical practice.

A systematic review by Girgis and Duarte (2018) assessed the efficacy of high-voltage monophasic pulsed current (HVMPC) to treat stage II to IV pressure ulcers, determine the HVMPC intervention parameters and best protocol, and identify other benefits and the safety of HVMPC. (10) Of the 11 eligible studies, 9 were RCTs and 2 were case series, which included a total of 483 patients. Five studies were included in the quantitative analysis (treatment arm n=137; control arm n=139). All studies found HVMPC had positive effects on wound surface area reduction and the incidence of complete healing, with a net effect on wound surface area

reduction of 5.4% per week. Of studies that reported adverse reactions to HVMPC, none were seen in 5 studies, with no patient discomfort reported, and minor adverse reactions were seen in 1 study; 3 studies concluded that HVMPC is safe.

A meta-analysis by Khouri et al. (2017) included 29 randomized trials (N=1510 patients; N=1753 ulcers) of individuals treated with electrostimulation, sham stimulation, or standardized wound care. (11) The primary finding was a highly heterogeneous overall standardized mean difference of 0.72. Modalities varied: in 18 studies, active electrostimulation was placed near the wound, and in 17 studies, electrostimulation was placed over the wound; additionally, types of waveforms varied between studies (types included direct-, high-, or low-voltage current, and alternating current). Electrostimulation had the greatest efficacy when the active electrode was placed over the wound, and high voltage pulsed current (HVPC) was used (standardized mean difference, 0.8; 95% confidence interval [CI], 0.38 to 1.21; I^2=79%). Other factors that may have affected the efficacy of electrostimulation were ulcer type, size, and duration (small, quick-healing pressure ulcers were favorable), although the association was not statistically significant (p=.28). In subgroup analyses, reviewers found a greater sensitivity for wound size area than for other outcomes. Potential sources of heterogeneity were electrode polarity, ulcer etiology, and type of outcome. Reviewers noted that 52% of the studies had a high risk of bias but concluded that the overall safety and efficacy of electrostimulation seem confirmed, given the current evidence.

A systematic review by Lala et al. (2016) addressed electrostimulation for treating pressure ulcers in individuals with spinal cord injury. (5) Fifteen studies met inclusion criteria; 6 were RCTs, 6 were prospective controlled trials, 2 were retrospective controlled trials, and 4 were case series. Several studies, published by the same research group and using the same populations, might have overlapped. Reviewers used a 10-point methodologic 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 electrostimulation than sham stimulation or usual care (relative risk, 1.55; 95% CI, 1.12 to 2.15). Several other pooled analyses assessed outcomes related to wound size (of less clinical interest) and data from nonrandomized studies.

A systematic review by Barnes et al. (2014) included RCTs evaluating the comparative effectiveness of electrostimulation for chronic ulcers of any etiology and standard treatment and/or sham stimulation. (1) Twenty-one trials were selected; 14 used pulsed currents, 5 used alternating currents, and 2 used direct currents. Pressure ulcers were evaluated 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 (i.e., 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, these studies reported outcomes related to the decrease in wound size. Meta-analyses were performed on several of these secondary outcomes. A pooled analysis of 6 studies (n=201) found that electrostimulation 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<.001), and heterogeneity among trials was not significant. Another pooled analysis of 6 RCTs (n=266) found that electrostimulation 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^2 (95% CI, 1.66 to 3.17 cm^2; p<.001) and there was significant heterogeneity. Reviewers conducted sensitivity analyses, and the significant benefit of electrostimulation on ulcer size remained when studies of pulsed current and direct current were analyzed separately. Limitations of the evidence base identified in the systematic review included few high-quality studies, variability in study designs, and lack of data on complete healing.

Tables 1 and 2 describe the characteristics and results of the 4 systematic reviews described above that had the least overlap and the most recent data.

Table 1. Characteristics of Key Systematic Reviews with Meta-Analyses on Electrical Stimulation to Treat Chronic Ulcers

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Zheng et al. (2022) (8)	Inception to July 2021	10	Patients with diabetes-related leg and foot ulcers	352 (19 to 56)	RCT	4 to 12 weeks
Arora et al. (2020) (9)	1985 to 2018	20	Patients with at least 1 pressure ulcer (no restrictions on the type or stage)	913 (NA)	RCTs, published and unpublished	NA
Girgis and Duarte (2018) (10)	1988 to 2017	11	Patients with stage II to IV pressure ulcers	483 (3 to 87)	RCTs, case series	4 to 22 weeks
Khouri et al. (2017) (11)	1985 to 2014	29	Adults with pressure, diabetic, or venous ulcers	1510 (NA)	RCTs	NA

NA: not available; RCT: randomized controlled trials; N: number.

Table 2. Results of Key Systematic Reviews with Meta-Analyses on Electrical Stimulation to Treat Chronic Ulcers

Study	Overall Efficacy	Wound Surface Area Reduction	Complete Healing	Proportion of Pressure Ulcers Healed
Zheng et al. (2022) (8)				
SMD		2.56		
95% CI		1.43 to 3.69		
p-value		<.001		

I^2		93.9%			
RR of non-healing				0.72	
95% CI				0.54 to 0.96	
p-value				.38	
I^2				2.3%	
Arora et al. (2020) (9)				**Time to complete healing**	
RR					1.99
95% CI					1.39 to 2.85
I^2					0%
HR				1.06	
95% CI				0.47 to 2.41	
I^2				0%	
Girgis and Duarte (2018) (10)					
		Treatment	**Control**		
Mean per week, %		12.39	6.961		
SD		2.46	1.76		
SEM		1	0.72		
95% CI		10.43 to 14.37	5.56 to 8.83		
RR				1.93	
95% CI				1.26 to 2.93	
p-value				.002	
Khouri et al. (2017) (11)					
SMD	0.72	1.21			
95% CI	0.49 to 0.95	0.82 to 1.60			
I^2	78%				

CI: confidence interval; I^2: indicates heterogeneity of studies; HR: hazard ratio; RR: risk ratio; SD: standard deviation; SEM: standard error of the mean; SMD: standard mean difference.

Section Summary: Electrostimulation

The evidence on the use of electrostimulation to treat wounds includes multiple systematic reviews of RCTs and other study designs. Many studies reported short-term outcomes such as wound healing rate or decrease in wound size; several meta-analyses of the trials found improvements for these outcomes. However, few studies included within meta-analyses evaluated complete healing or time to complete healing, 2 more clinically important outcomes.

In 1 meta-analysis, the time to complete wound healing did not reach statistical significance in favor of electrostimulation for the treatment of pressure ulcers. Systematic reviews were limited by the inclusion of studies with poor methodological quality and high heterogeneity.

Electromagnetic Therapy

Clinical Context and Therapy Purpose

The purpose of electromagnetic therapy is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with any wound type (acute or nonhealing).

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with any wound type (acute or nonhealing).

Interventions

The therapy being considered is electromagnetic therapy.

Comparators

Comparators of interest include standard wound care.

Outcomes

The general outcomes of interest are symptoms, change in disease status, morbid events, QOL, and treatment-related morbidity.

Follow-up over months is of interest for electromagnetic therapy to monitor relevant outcomes.

Review of Evidence

Systematic Reviews

Two Cochrane reviews have evaluated electromagnetic therapy for treating wounds: 1 addressed the treatment of pressure ulcers (last updated in 2015) and the other addressed leg ulcers (last updated in 2015). (12, 13) Each review identified a few RCTs (2 and 3 studies, respectively) with small sample sizes. Consequently, these reviewers were unable to conduct robust pooled analyses of study findings. Both concluded that there is insufficient evidence that electromagnetic therapy is effective for treating chronic wounds.

Randomized Controlled Trials

Khooshideh et al. (2017) reported on a RCT of 72 women treated with pulsed electromagnetic field (PEMF) therapy or sham PEMF following Cesarean section. (14) The primary outcome was a reduction of pain during recovery, which was assessed using a visual analog scale (VAS) at regular intervals for 7 days following surgery. At each assessment, women treated with PEMF (n=36) reported significantly lower levels of pain than did their counterparts treated with sham (n=36). For example, 2 hours after surgery, PEMF patients had a mean VAS score of 53

compared with that of sham patients (VAS score, 63; p=.01). Comparisons were similar between groups through the seventh day of follow-up, when the PEMF group reported a mean VAS score of 0.8 and the sham group reported a mean VAS score of 3 (p=.01). The percentage of patients who reported severe pain (defined as VAS score, ≥75) 24 hours or less after surgery was lower in the PEMF group (36%) than in the sham group (72%; p=.002). Secondary outcomes were wound healing and use of the pain medication available to each patient at discharge (diclofenac suppository 100 mg as needed); unlike other outcomes, wound healing was assessed 10 days after surgery, rather than 7. None of the patients in the PEMF group showed signs of wound exudate or edema, compared with 13% and 11% of sham patients who had exudate or edema, respectively (p=.04). Patients in the PEMF group consistently used fewer suppositories to treat postoperative pain (mean, 1.7) than those treated with sham (mean, 3.7; p<.001). Patients in both groups took an average of 3 to 4 days before they were able to resume normal activities, with no significant difference between groups (p=.58).

Section Summary: Electromagnetic Therapy

The evidence on the use of electromagnetic therapy includes 2 systematic reviews of RCTs (1 on pressure ulcers and the other on leg ulcers) and a RCT of electromagnetic treatment following Cesarean section. The reviews were limited by the inclusion of small studies and a lack of robust pooled analyses. The RCT was focused primarily on postoperative pain, with wound healing being a secondary outcome that was assessed according to a previous protocol. The evidence on the use of electromagnetic therapy to treat wounds is inadequate to support drawing a conclusion about efficacy.

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.

Practice Guidelines and Position Statements

American College of Physicians

In 2015, the American College of Physicians (ACP) published guidelines on the treatment of pressure ulcers. (15) The guidelines recommended that 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. This guideline is listed as "inactive" on the ACP website. (16)

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. (17) 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. (18) 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. (19) 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. (20) 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.

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. (21)

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 ClinicalTrials.gov in November 2024 did not identify any ongoing or unpublished trials that would likely influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	97014, 97032
HCPCS Codes	A4595, A4630, E0720, E0730, E0761, E0769, G0281, G0282, G0295, G0329

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
06/15/2025	Document updated with literature review. Coverage unchanged. Reference 20 and 21 added.
11/15/2024	Document updated with literature review. Coverage unchanged. No new references added.
01/01/2024	Document updated with literature review. Coverage unchanged. Reference 8 added, others removed.
04/15/2022	Document updated with literature review. Coverage unchanged. Reference 16 added, and others updated.
04/01/2021	Document updated with literature review. Coverage unchanged. References 8 and 9 added. Some references updated and others removed.
07/15/2020	Reviewed. No Changes.
04/15/2019	Document updated with literature review. Coverage unchanged. Added references 9-10, 13, and 15; others updated. Title changed from "Electrostimulation and Electromagnetic Therapy for the Treatment of Chronic Wounds".
06/15/2018	Reviewed. No Changes.
09/01/2017	Document updated with literature review. Coverage unchanged.
05/15/2016	Reviewed. No changes.
01/01/2015	Document updated with literature review. Coverage clarified in the first coverage statement to specify; including but not limited to the types of electrical stimulation mentioned.
10/15/2013	Document updated with literature review. Coverage unchanged.
06/01/2008	Policy reviewed without literature review; new review date only.
09/01/2007	Revised/updated entire document
12/01/2005	New medical document