2.01.57 Electrostimulation and Electromagnetic Therapy for Treating Wounds			
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Section:	2.0 Medicine	**Page:**	Page 1 of 14

Policy Statement

Electrical stimulation for the treatment of wounds, is considered **investigational** including but not limited to, **any** of the following:

I. Alternating current (AC)
II. High-voltage pulsed current (HVPC)
III. Low-intensity direct current (LIDC)
IV. Transcutaneous electrical nerve stimulation (TENS)

Electrical stimulation performed by the patient in the home setting for the treatment of wounds is considered **investigational**.

Electromagnetic therapy for the treatment of wounds is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

The following HCPCS codes are available for this treatment:

- **E0761**: Nonthermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device
- **E0769**: Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
- **G0281**: Electrical stimulation, (unattended), to one or more areas, for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care
- **G0282**: Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281
- **G0295**: Electromagnetic therapy, to one or more areas, for wound care other than described in G0329 or for other uses
- **G0329**: Electromagnetic therapy, to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care

The HCPCS code G0281 (unattended electrical stimulation) was specifically developed to distinguish between attended and unattended electrical stimulation. Attended electrical stimulation is identified by CPT code 97032. Although the description of this CPT code is non-specific and could describe any type of electrical stimulation, electrical stimulation for wound healing would not require constant attendance, and thus the CPT code would not be applicable.

The Medicare policy notes that coverage for electrical stimulation is limited to supervised settings. Although the terminology is confusing, for Medicare policy, supervised is interpreted to mean that while a physician or other health professional is supervising the treatment, this person does not have to be in constant attendance. Therefore, to implement the Medicare policy, "supervised" essentially means "unattended" as described in the G code.

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.

Related Policies

- Negative Pressure Wound Therapy in the Outpatient Setting
- Noncontact Ultrasound Treatment for Wounds

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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

Background
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.

Literature Review
Evidence reviews assess the clinical evidence to determine whether the use of 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 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. RCTs 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 patients with any wound type (acute or nonhealing).

The question addressed in this evidence review is: Does electrostimulation improve the net health outcome in individuals with acute or nonhealing wounds?

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

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.

Patients with any wound type (acute or nonhealing) are actively managed by primary care providers and wound specialists in an outpatient clinical setting.

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,-,7,]

Systematic Reviews
Aurora 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.[8,] 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 >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.[9,]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.[10,] 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 waveform 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 3 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
Arora et al (2020)[8]	1985 to 2018	20	Patients with at least 1 pressure ulcer (no restrictions on the type or stage)	N=913 (NA)	RCTs, published and unpublished	NA
Girgis & Duarte (2018)[9]	1988 to 2017	11	Patients with stage II to IV pressure ulcers	N=483 (3 to 87)	RCTs, case series	4 to 22 weeks
Khouri et al (2017)[10]	1985 to 2014	29	Adults with pressure, diabetic, or venous ulcers	N=1510 (NA)	RCTs	NA

NA: not available; RCT: randomized controlled trial.

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
Arora et al (2020)[8.]				*Time to complete healing*	
RR					1.99
95% CI					1.39 to 2.85
I2					0%
HR				1.06	
95% CI				0.47 to 2.41	
I2				0%	
Girgis & Duarte (2018)[9.]					
		Treatment	Control		
Mean per wk, %		12.39	6.961		
SD		2.46	1.76		
SEM		1	0.72		
95% CI		10.43 to 14.37	5.56 to 8.38		
RR				1.93	
95% CI				1.26 to 2.93	
P-value				.002	
Khouri et al (2017)[10.]					
SMD	0.72	1.21			
95% CI	0.49 to 0.95	0.82 to 1.60			
I2	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.

Randomized Controlled Trials

Houghton et al (2010) in Canada published a single-blind trial evaluating the effect of adding treatment with HVPC to a community-based standard wound care program.[Houghton PE, Campbell KE, Fraser CH, et al. Electr.... ; 91(5): 669-78. PMID 20434602] The trial included 34 adults with spinal cord injuries and stage II to IV pressure ulcers of at least 3 months in duration. The trial excluded potential participants who were likely to have limited healing potential (e.g., 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 (e.g., overnight). A compliance analysis 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 (the percentage decrease in wound care surface) was significantly greater in the group receiving HVPC (n=16) than in the standard care only group (n=18) (mean decrease, 70% versus 36%, respectively; p=0.048). By 3 months, all 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 (80%) of 15 in the HVPC group and 5 (36%) of 14 in the standard care only group; this difference was statistically significant (p=0.02). There was

no statistically significant difference in the number of wounds completely healed at 3 months: 6 in the HVPC group and 5 in the standard care only group.

Franek et al (2012) in Poland evaluated high-voltage electrical stimulation for treating lower-extremity pressure ulcers in an unblinded RCT.[Franek A, Kostur R, Polak A, et al. Using high-vol.... 2; 58(3): 30-44. PMID 22391955] Fifty-seven patients with stage II or III pressure ulcers were randomized to electrostimulation plus standard wound care or standard care only. The electrical stimulation intervention involved 5, 50-minute procedures per week until the wound was healed or until a maximum of 6 weeks. Fifty (88%) of 57 patients completed treatment. After 6 weeks, there were statistically, significantly greater changes in the treatment group than in the control group on several outcomes. These included a change in wound surface area (88.9% versus 44.4%, p<0.001) and change in the longest length of the wound (74.0% versus 36.1%, p<0.001), respectively. The rate of complete healing was not reported because trialists were unable to follow patients long enough for healing to occur.

Polak et al (2017) conducted a prospective RCT in which 63 patients were randomized to cathodal or cathodal plus anodal electrostimulation by HVMPC or sham stimulation.[Polak A, Kloth LC, Blaszczak E, et al. The Efficac.... 97(8): 777-789. PMID 28789467] All patients had pressure ulcers of 0.5 cm^2 or greater on the pelvic girdle, and most patients (n=49 [77.78%]) were immobile; also, regardless of the regimen administered, standard wound care was given to all patients. Of patients who received HVMPC, 23 were given daily 50-minute treatments of cathodal electrostimulation 5 times per week for 6 weeks; a comparator group (n=20) was given cathodal stimulation for 1 week, then anodal stimulation for 5 weeks. No statistically significant differences in wound-related outcomes were observed between cathodal and cathodal-anodal groups, although outcomes in both groups were significantly superior to those for the group receiving sham stimulation. Decreases in wound size area of 82.34% and 70.77% for the cathodal and cathodal-anodal groups, respectively, were significantly larger than the decrease observed in the placebo group (40.53%). Similarly, the HVMPC groups achieved a 50% decrease in wound size area faster (1.92 weeks and 2.60 weeks) than the sham group (10.60 weeks). During the 6 weeks of treatment, 47.83% of wounds treated with cathodal stimulation closed, as did 45% of those treated with cathodal-anodal stimulation. For the sham group, none of the patients achieved full wound closure at 6 weeks. These results would suggest that the active stimulation protocols were comparable in efficacy and superior to standard wound care. Limitations of the trial were that the authors did not confirm blinding rates or follow patients to complete wound closure, so the optimal treatment time was not determined.

Section Summary: Electrostimulation
The evidence on the use of electrostimulation to treat wounds includes systematic reviews and RCTs. 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 patients with any wound type (acute or nonhealing).

The question addressed in this evidence review is: Does electromagnetic therapy improve the net health outcome in individuals with acute or nonhealing wounds?

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

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

Interventions
The therapy being considered is electromagnetic therapy.

Patients with any wound type (acute or nonhealing) are actively managed by primary care providers and wound care specialists in an outpatient clinical setting.

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 2012) and the other addressed leg ulcers (last updated in 2015).[11,12] 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
Khooshidehet al (2017) reported on a RCT of 72 women treated with pulsed electromagnetic field (PEMF) therapy or sham PEMF following Cesarean section.[13] 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 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
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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.[14] 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. [15]

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.[16] 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.[17] 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.[18] 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.[19] 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 2021 did not identify any ongoing or unpublished trials that would likely influence this review.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	97014	Application of a modality to 1 or more areas; electrical stimulation (unattended)
	97032	Application of a modality to 1 or more areas; electrical stimulation (manual), each 15 minutes
HCPCS	E0761	Nonthermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device
	E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
	G0281	Electrical stimulation, (unattended), to one or more areas, for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care, as part of a therapy plan of care

Type	Code	Description
	G0282	Electrical stimulation, (unattended), to one or more areas, for wound care other than described in G0281
	G0295	Electromagnetic therapy, to one or more areas, for wound care other than described in G0329 or for other uses
	G0329	Electromagnetic therapy, to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
08/01/2005	Policy adopted. MPC accepted as CTAF consent BCBSA TEC Vol. 20, No.2
10/01/2005	Policy Revision
04/03/2009	Policy Revision
10/14/2009	Coding Update
01/06/2012	Policy title change from electrostimulation and electromagnetic therapy for the treatment of chronic wounds without position change.
07/31/2015	Coding Update
12/04/2015	Policy title change from Electrostimulation and Electromagnetic Therapy for the Treatment of Wounds Policy revision without position change
04/01/2016	Policy revision without position change
05/01/2017	Policy revision without position change
11/01/2017	Policy revision without position change
03/01/2018	Policy revision without position change
03/01/2019	Policy revision without position change
04/01/2020	Annual review. No change to policy statement. Literature review updated.
03/01/2021	Annual review. No change to policy statement. Literature review updated.
03/01/2022	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) 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 the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment,

procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. 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 covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Electrostimulation and Electromagnetic Therapy for Treating Wounds 2.01.57 **Policy Statement:** Electrical stimulation for the treatment of wounds, is considered **investigational**, including but not limited to, **any** of the following: • Alternating current (AC) • High-voltage pulsed current (HVPC) • Low-intensity direct current (LIDC) • Transcutaneous electrical nerve stimulation (TENS) Electrical stimulation performed by the patient in the home setting for the treatment of wounds is considered **investigational**. Electromagnetic therapy for the treatment of wounds is considered **investigational**.	**Electrostimulation and Electromagnetic Therapy for Treating Wounds 2.01.57** **Policy Statement:** Electrical stimulation for the treatment of wounds, is considered **investigational** including but not limited to, **any** of the following: I. Alternating current (AC) II. High-voltage pulsed current (HVPC) III. Low-intensity direct current (LIDC) IV. Transcutaneous electrical nerve stimulation (TENS) Electrical stimulation performed by the patient in the home setting for the treatment of wounds is considered **investigational**. Electromagnetic therapy for the treatment of wounds is considered **investigational**.