Molina Clinical Policy
Electrostimulation and Electromagnetic Therapy for Wound Care: Policy No. 399

Last Approval: 8/9/2023
Next Review Due By: August 2024

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

The integumentary system operates within its own natural electrical environment sometimes referred to as the “skin battery.” The endogenous electrical field is integral in wound healing as a cue for cellular migration, and for promoting angiogenesis, collagen synthesis, and the proliferation of fibroblasts (Rajendran et al. 2021). Risk factors for impaired wound healing disrupt the natural healing methods of the body resulting in chronic non healing wounds.

In an economic evaluation of 2014 Medicare costs conducted by Nussbaum et al. (2018) spending estimates for chronic non healing wounds were $28-96 billion dollars annually. Wound care and the accompanying complications comprise a sizable portion of healthcare expenditures and decrease quality of life for those affected, leading scientists to investigate if exogenous electrical sources can aid in wound repair. Electrostimulation and electromagnetic therapy are technologies exploring new modalities for wound healing. Both modalities are considered adjunct therapies and are not a substitute to standard wound care.

Standard wound care includes optimization of nutritional status, debridement, moist dressings to maintain a clean moist wound environment to promote healing, and necessary treatment to prevent or resolve any infection that may occur. Wound care includes relieving pressure to prevent further breakdown by position changes at least every two hours, offloading pressure as much as possible, maintaining tight glycemic control for diabetic patients, optimizing perfusion for arterial ulcers, and use of a compression system for patients with venous ulcers (CMS 2004 & 1996)

Electrostimulation (ES) is the application of electrical current through electrodes placed directly to the wound or peri wound area. There are varied parameters for applying electrical current including direct current (DC), high voltage pulsed current (HVPC), alternating current (AC) and transcutaneous electrical nervous stimulation (TENS). The frequency, polarity, pulse type, amplitude, and duration of treatment may vary as well (Ontario 2017; Rajendran et al. 2021).

Electromagnetic therapy (EMT) or pulsed electromagnetic field (PEMF) is the application of electromagnetic fields around the wound, rather than direct electrical current (Aziz 2015).

Regulatory Status

The Food and Drug Administration (FDA) has not approved any electrical stimulation or electromagnetic devices for the treatment of chronic wounds.

COVERAGE POLICY

This policy applies to Medicaid and Marketplace Members only. For Medicare, reference *CMS NCD No. 270.1.*

Electrostimulation therapy for wound care may be considered medically necessary for up to 30 consecutive days when ALL the following criteria are met (initial treatment):

1. Diagnosis of **ONE** of the following:
    a. Arterial ulcer **OR**
    b. Chronic Stage III or Stage IV pressure injury **OR**
    c. Diabetic ulcer **OR**
    d. Venous stasis ulcer
2. Standard wound care* has been administered under the supervision of a healthcare professional for 30 consecutive days without documented measurable signs of healing**.;**
3. Electrostimulation therapy is performed under direct supervision of a healthcare professional in an inpatient, outpatient, or office setting.

Electrostimulation therapy for wound care may be considered medically necessary for longer than 30 consecutive days when ALL the following criteria are met:

1. Treating physician documents measurable signs of healing* at least once per month **AND**
2. Electrostimulation therapy is performed under direct supervision of a healthcare professional in an inpatient, outpatient, or office setting.

Electrostimulation therapy must be discontinued when the wound demonstrated a 100% epithelialized wound bed
OR
The wound displays no measurable signs of healing after 30 consecutive days of appropriate electrostimulation therapy.

*Reference Supplemental Information section for further information on standard wound care and measurable signs of healing.

Electromagnetic therapy for wound care performed in any setting **is experimental, investigational, and unproven,** including venous stasis ulcers, arterial ulcers, diabetic foot ulcers, chronic pressure injuries and soft tissue injuries due to insufficient evidence in the peer reviewed medical literature.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Electrostimulation (ES)

While evidence does not reveal definitive optimal treatment parameters for applying ES therapy, it does reveal that ES can be an effective adjunct therapy to standard wound care in accelerating the healing of chronic hard to heal wounds. The evidence is inconclusive for ES used in the treatment of wounds other than chronic non healing wounds.

Systematic Reviews
Borges et al. (2023) conducted a systematic review of the effect of electrical stimulation in healing venous leg ulcers. The review included eight randomized controlled trials (RCTs) and three case series for 724 limbs with venous leg ulcers in 716 patients. The mean age was 64.2 years and 46.2% were men. The RCTs placed the electrodes in one of three positions: active electrode was placed on the wound with the passive electrode placed on healthy skin (n = 6), the two electrodes were placed on either side of the wound edges (n = 4), or a planar probe was used (n=1) with pulsed current being the most utilized method of current delivery. Change in ulcer size, ulcer healing rate, exudate

levels, and/or healing time were the measurements used to determine outcome. Five of the RCTs detected a statistically significant improvement in at least one venous leg ulcer healing measurement after ES. Two RCTs found ES improved wound healing only in patients who had not undergone surgical treatment for venous leg ulcers.

Melotto et al. (2022) conducted a systematic review on the effects of electrical stimulation on diabetic ulcers of the foot and lower limb. The review included five RCTs, one prospective study, and one retrospective study for seven articles analyzed, with the smallest sample size being 20 and the largest being 114 participants. While all wounds, neuropathic and ischemic, exhibited faster healing rate with ES paired with standard wound care, only diabetic wounds of ischemic etiology showed statistically significant increased healing rate when treated with ES combined with standard wound care compared to standard wound care alone. The limitations to this review included differing study methodologies, varying diabetic ulcer origin, and the small number of studies included in the review.

Rajendran et al. (2021) conducted a systematic review on electrical stimulation to enhance wound healing. The review included 30 full text articles and was conducted in two parts. Part one focused on the impact of ES on the process of normal wound healing and included in vitro studies and studies conducted on human skin. Part two reviewed the effects of ES on chronic wound healing and included in vivo RCTs on human participants.

> Part one: Six in vitro studies reviewed in part one exhibited bacteriostatic effects when common bacterial strains from chronic wounds were subjected to ES. The bacteriostatic effects were dependent on the amount and method of ES deliverance. There is a lack of in vivo studies to investigate the antibacterial effects of ES on chronic wounds, but the in vitro evidence is promising. Four RCTs and one case series revealed ES has positive effects on tissue perfusion. Two RCTs revealed a histological increase in vascular endothelial growth factor, endothelial cells, blood flow, and an upregulation on anti-inflammatory genes in biopsy wound samples (two samples taken per participant, therefore the participants were their own controls) exposed to ES.
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> Part two: Twelve RCTs with a total of 532 participants were analyzed for effects of ES on chronic wound healing. All studies randomized participants to receive ES or sham treatment in combination with standard wound care. All studies reported a degree of accelerated wound healing in those with ES therapy compared to sham treatment. The limitation of this review was all the studies utilized different types and currents of ES therapy, as well as varied durations and outcome measurements.

Randomized Controlled Trials (RCTs)

Avendano - Coy et al. (2022) conducted a double blind RCT to evaluate the effectiveness of microcurrent therapy for treating pressure injuries. Participants were volunteers from several nursing homes above the age of 65 with pressure injuries, only 30 of which passed inclusion criteria. The 30 participants were split randomly into two groups: the experimental group (EG) received ES therapy with standard wound care and the placebo group (PG) received sham therapy with standard wound care. The study evaluated the wounds via the Pressure Ulcer Scale for Healing (PUSH) and the surface, depth, grade, and number of ulcers that healed completely. The wounds were evaluated three times, once pre-intervention, again 14 days after intervention start, and last 1 day after intervention completion. The intervention period lasted 25 days with the EG receiving 10h of microcurrent therapy, and the PG receiving 10h of sham stimulation. At 14 days the PUSH improvement was 16.8% higher in the EG versus PG. At 1 day post intervention the PUSH improvement was 25.3% greater in the EG versus the PG, and a 28.6% greater wound area reduction was exhibited in the EG versus PG. The limitations of this study are small sample size, risk of selection bias, short follow up duration, and varying underlying disease processes between the two groups as 53% of the experimental group had diabetes compared to 13% of the sham group.

Polak et al. (2018) conducted a double blind RCT to study the effect of anodal versus cathodal electrical stimulation on peri wound skin blood flow and pressure injury size reduction in persons with neurological injury. Sixty-one participants met inclusion criteria from a single inpatient rehabilitation unit. In this double blind RCT, participants were randomly placed into three groups: anodal (AG), cathodal (CG), or placebo (PG) ES. All groups received their standard wound care in addition to their respective therapy for 50 minutes a day, five days per week, for eight weeks maximum. Peri wound blood flow was measured via Doppler at baseline, week 2, and week 4. Wound surface area was obtained and analyzed using a digitizer connected to a personal computer at baseline and week 8. Pressure injuries were in a baseline size range 1.01 cm2 to 59.57 cm2; duration 4 to 48 weeks, 73.77% of which were in the sacral region. At

week 2 peri wound blood flow was significantly higher in the AG and CG than in the PG (P <.05), while at week 4 and 8 the findings were positively correlated but not more statistically significant than the PG group. Wound surface area reduction was statistically significant for both the AG (64.10% ± 29.22%) and CG (74.06% ± 23.23%) in comparison to the PG group (41.42% ± 27.88%; P = .0391 and P = .0024, respectively). The results showed both modes of ES increased peri wound blood flow and decreased wound size, however the limitations of this study were the small sample size, risk of selection and attrition bias, and the study duration was insufficient for all the pressure injuries to close.

Polak et al. (2016) conducted a double blind RCT to study the effect of cathodal high voltage monophasic pulsed current on the healing process of pressure injuries. Forty-nine participants met the criteria of having pressure injuries unresponsive to standard wound care for the previous four weeks prior to the study. The participants were randomly assigned to be in the group to receive electrostimulation therapy or sham treatment group. Treatment was administered for 50 minutes a day, five days a week, for six weeks. The pressure injuries were measured at baseline, week one, and week six. There was a statistically significant decrease in percent of wound size reduction in the ES group of 35% ± 30.5% compared with 17.07% ± 34.13% in the control group (P = .032). Upon completion of the study at week six, the ES group saw an 80.31% ± 29.02% percentage of wound size reduction versus 54.65% ± 42.65% in the control group (P = .046). The limitations of this study are small sample size and risk of selection bias.

Houghton et al. (2010) conducted a three-month single blind RCT in a community-based home care setting in spinal cord injury patients with chronic pressure injuries. The participants were randomly placed into a group to receive standard wound care alone or ES with standard wound care. Wound healing was measured by wound size reduction and improvement in wound appearance at baseline and three months. The percentage decrease in wound surface area (WSA) at the end of the intervention period was significantly greater in the ES + standard wound care group (mean +/- SD, 70+/-25%) than in the standard wound care group (36+/-61%; P=.048). Wound appearance assessed using the photographic wound assessment tool was improved in wounds treated with ES + standard wound care but not standard wound care alone. The limitations of this study are small sample size, and risk for selection and detection bias.

Electromagnetic Therapy (EMT)

For EMT, the available evidence is insufficient to support conclusions regarding the efficacy of this technology for the treatment of chronic wounds and soft tissue injuries. The available information from clinical trials is insufficient to prove safety, efficacy, define optimal treatment protocols, establish patient selection criteria, or to evaluate the relative efficacy of this therapy compared with other treatment options. The available studies were small and significant methodological flaws were noted between intervention and control groups. Therefore, it is not possible to draw valid conclusions about the efficacy and safety of this technology.

Aziz et al. (2015) performed a systematic review to assess the effects of EMT on the healing of venous leg ulcers. Three RCTs of low or unclear risk of bias, involving 94 people, were included in the original review; subsequent updates have identified no new trials. All the trials compared the use of EMT with sham-EMT. Meta-analysis of these trials was not possible due to heterogeneity. In the two trials that reported healing rates; one small trial (44 participants) reported that significantly more ulcers healed in the EMT group than the sham-EMT group however this result was not robust to different assumptions about the outcomes of participants who were lost to follow up. The second trial that reported numbers of ulcers healed found no significant difference in healing. The third trial was also small (31 participants) and reported significantly greater reductions in ulcer size in the EMT group, however this result may have been influenced by differences in the prognostic profiles of the treatment groups. The conclusion of this review indicated that it is not clear whether EMT influences the rate of healing of venous leg ulcers. Further research would be needed to answer this question.

Aziz et al. (2013) performed a systematic review to assess the effects of EMT on the healing of pressure ulcers. Two randomized controlled trials, involving 60 participants, at unclear risk of bias were included in the original review. Both trials compared the use of EMT with sham EMT, although one of the trials included a third arm in which only standard therapy was applied. Neither study found a statistically significant difference in complete healing in people treated with EMT compared with those in the control group. In one trial that assessed percentage reduction in wound surface area, the difference between the two groups was reported to be statistically significant in favor of EMT. However, this result should be interpreted with caution as this is a small study, and this finding may be due to chance.

Additionally, the outcome, percentage reduction in wound area, is less clinically meaningful than complete healing. The results provide no strong evidence of benefit in using EMT to treat pressure ulcers. However, the possibility of a beneficial or harmful effect cannot be ruled out because there were only two trials included, both with methodological limitations and small numbers of participants. Further research is recommended.

The American College of Physicians (ACP) developed a guideline to present the evidence and provide clinical recommendations based on the comparative effectiveness of treatments of pressure ulcers. Based on the evidence, the ACP recommends that moderate-quality evidence showed that electrical stimulation accelerated wound healing as an adjunctive therapy, and low-quality evidence showed no difference or mixed findings for the other adjunctive therapies assessed, including electromagnetic therapy (Qaseem et al. 2015).

SUPPLEMENTAL INFORMATION

Standard wound care includes:

1. Optimization of nutritional status **AND**
2. Maintenance of a clean moist wound bed with appropriate moist dressings **AND**
3. Necessary treatment to resolve any infection present **AND**
4. Debridement of devitalized tissue **AND**
5. Appropriate pressure offloading of wound **AND**
6. Wound care for specific wounds:
    a. For arterial ulcers: assessment of individual's vascular status and correction of any amenable vascular problems to establish adequate perfusion; **OR**
    b. For venous ulcers: compression dressing/garments consistently applied; **OR**
    c. For pressure injuries: frequent repositioning at least every two hours; **OR**
    d. For diabetic ulcers: Improved glycemic control as exhibited by efforts shown to maintain blood glucose levels below 200mg/dL and/or a glycosylated hemoglobin level (HbA1c) of 9% or less within the last 90 days.

Measurable signs of healing

1. Decrease in wound size, surface area or volume; **AND/OR**
2. Decrease in exudate amount; **AND/OR**
3. Decrease in necrotic tissue amount.

Pressure Injury Staging:

Stage III Pressure Injury: Full thickness injury. Adipose tissue exposed with granular tissue and rolled wound edges often present. Slough and/or eschar may be present.

Stage IV Pressure Injury: Full thickness injury and tissue loss. Bone, cartilage, fascia, ligament, muscles, and/or tendon exposed. Rolled wound edges and tunneling are often present. Slough and/or eschar may be present.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

HCPCS (Healthcare Common Procedure Coding System) Codes

HCPCS	Description
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
E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

8/09/2023 Policy reviewed. Changes to coverage criteria. IRO reviewed June 30, 2023.
8/10/2022 Policy reviewed and updated. No changes to coverage position. References updated.
8/11/2021 New policy. IRO Review: policy reviewed on February 24, 2021 by a board-certified physician in the areas of Surgery General (Wound Care).

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*