



Electromagnetic Therapy for Wounds (for Louisiana Only)

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[➔ Instructions for Use](#)

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Application

This Medical Policy only applies to the state of Louisiana.

Coverage Rationale

Electromagnetic therapy is unproven and not medically necessary due to insufficient evidence of efficacy for treating wounds or ulcers including but not limited to:

- Arterial ulcers
- Chronic pressure ulcers
- Diabetic foot ulcers
- Soft tissue injuries
- Venous stasis ulcers

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPSC Code	Description
*E0769	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
G0295	Electromagnetic therapy, to one or more areas, for wound care other than described in G0329 or for other uses

HCPSC Code	Description
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

Codes labeled with an asterisk (*) are not on the State of Louisiana Medicaid Fee Schedule and therefore may not be covered by the State of Louisiana Medicaid Program.

Description of Services

Electromagnetic therapy refers to the application of electromagnetic fields to the wound area, rather than direct application of electrical current. This procedure is also referred to as pulsed electromagnetic induction (PEMI), pulsed electromagnetic field (PEMF), and pulsed electromagnetic therapy. ECRI (2018).

Clinical Evidence

There is limited evidence in the published scientific literature to support the use of electromagnetic therapy (**EMT**) for treating chronic wounds and ulcers. The data from clinical trials are insufficient to prove efficacy or to evaluate the effects of this therapy compared with other treatment options.

Wang et al. (2024) conducted a systematic review and meta-analysis, which included the Aziz and Cullum, 2015 study below, to assess the impact of electromagnetic therapy on venous leg ulcers (VLUs). The review comprised five studies. While some studies indicated that EMT might accelerate wound healing, the overall evidence was deemed inconclusive. The authors suggested that future research should aim to standardize research designs and protocols for EMT application in VLU treatment, use larger sample sizes to enhance the power and validity of results, and include long-term follow-up periods to evaluate the durability of EMT effects on VLUs and identify any delayed adverse effects or long-term benefits. The review's limitations included moderate evidence quality, mainly due to small sample sizes and variability in study designs.

A systematic review of randomized controlled trials was performed by Kull et al. (2023) to evaluate the impact of PEMF therapy on pain and function in patients with non-specific low back pain. Nine randomized controlled trials involving 420 participants were reviewed. The studies compared various combinations: PEMF versus placebo-PEMF, PEMF combined with conventional physical therapy versus conventional physical therapy alone, PEMF and conventional physical therapy versus placebo-PEMF and conventional physical therapy, PEMF versus high-intensity laser therapy (HILT) versus conventional physical therapy, and osteopathic manipulative treatment (OMT) combined with PEMF versus PEMF alone versus placebo-PEMF versus OMT alone. No serious adverse effects were reported in any of the nine trials. The authors found five of the nine studies demonstrated statistically significant reductions in pain and improvements in physical function compared to control groups ($p < 0.05$). However, the authors noted considerable heterogeneity among the study groups. They concluded that PEMF appears to be a beneficial therapy for pain relief and enhancing physical function in patients with non-specific low back pain, particularly when used alongside conventional physical therapies. They recommended further high-quality studies with larger sample sizes and standardized protocols. The review's limitations included the small number of participants, high heterogeneity of PEMF interventions, controlled therapies, and treatment regimens. Additionally, the intervention periods were short, and none of the studies included long-term follow-up. The primary limitation of this systematic review was the limited number of studies available for inclusion.

A Cochrane Database systematic review was conducted to assess the effects of EMT on the healing of venous leg ulcers (Aziz and Cullum, 2015). Three randomized controlled trials comparing EMT with sham-EMT or other treatments, involving 94 individuals, were included. At day 50, 2/10 (20%) venous ulcers were healed in the EMT group compared with 2/9 (22%) in the sham-EMT group. Assessment at 90 days found that 12/18 (67%) ulcers had healed in the EMT group compared with 6/19 (32%) in the sham group. No trials reported any evaluation of the precision of the reduction in wound size (change from baseline). Quality of life using a validated scale was not measured in any of the studies. At the end of the study, pain was reported to be lower in both the EMT and sham-EMT groups but the difference between the

groups was not significant. The authors concluded that there is no high-quality evidence about whether EMT speeds the healing of venous leg ulcers, and its effect is unclear. They recommend methodologically sound and robust **randomized controlled trials (RCTs)** are needed in order to investigate further any effect of using EMT to improve venous leg ulcer healing. There were several study limitations. This is a small study which did not conduct an intention to treat analysis. The methods for handling missing data in the trials varied and there was missing data in each arm. Another concern was that two of the studies were sponsored by the manufacturer of the electromagnetic devices.

In a Cochrane systematic review (Aziz and Bell-Syer, 2015) the effects of EMT on the healing of pressure ulcers was assessed. This review involved 60 participants and included two randomized controlled trials comparing the use of EMT with sham EMT, no EMT or treatments considered to be standard of care. One trial reported 17/20 (85%) ulcers in the EMT group achieved complete healing within the duration of treatment when compared with no ulcers healing in either of the other two groups. The reported risk ratio (RR) was 10.00 (95% CI 0.70 to 143.06). The authors reported findings between both groups were statistically not significant. The second trial reported 3/10 (30%) Stage II pressure ulcers and 3/5 (60%) Stage III ulcers in the EMT group healed in comparison to none in the sham EMT group. The pooled RR for Stage II and III was 7.00 (95% CI 0.97 to 50.38). The authors concluded the reported results of these two studies did not indicate healing of pressure ulcers was statistically significant when treated with EMT. No secondary outcomes including costs, quality of life, pain and acceptability of treatment were assessed in either trial. The authors further reported these two trials did not include strong evidence to support EMT speeds pressure healing. The trials included small numbers of participants and different regimens of treatment over different time scales. They added further trials comparing EMT with sham therapy, or standard of care, are needed to establish whether or not EMT improves the healing of pressure ulcers. They reported several study limitations including unclear risk of bias for blinding. While allocation to treatment groups was identified as randomized there was no clear description on how the randomization was accomplished and outcome data was incomplete.

Kwan et al. (2015) performed prospective, randomized, double-blind controlled study to examine the effectiveness of pulsed electromagnetic field (PEMF) therapy in the management of diabetic foot ulcers (DFUs), as compared with a control group. The study included 13 individuals- (7 in the PEMF group and 6 in the control group) diagnosed with type 2 diabetes and unsatisfactory healing of ulcer(s) in the preceding 4 weeks. Participants were randomly allocated to receive either active PEMF therapy (duration: 60 minutes; frequency: 12 Hz; intensity: 12 Gauss) or nonactive PEMF for 14 sessions within 3 weeks. Assessment on wound closure, wound depth, and microcirculation were performed at the baseline, end of the treatment period, and 1-month follow-up. At the posttreatment evaluation, the PEMF group demonstrated an 18% decrease, and the control group showed a 4% decrease over time. At the 1-month follow-up, the average wound size of the PEMF group decreased by 35%. The control group followed a similar trend. By the end of the treatment period, there was an 18% decrease in wound size in the active PEMF group as compared with a 10% decrease in the control group. The PEMF group demonstrated an increase in cutaneous capillary blood velocity (by 28%) and 14% increase in capillary diameter. The control group showed a decrease in both capillary blood velocity and diameter. The authors concluded that PEMF seems to produce a favorable influence on accelerating wound closure, decreasing wound depth, and increasing microcirculation. Limitations of this study include the small sample size and the different location on the feet of the ulcers which could affect the treatment outcome.

Clinical Practice Guidelines

International Working Group on the Diabetic Foot (IWGDF)

The International Working Group on the Diabetic Foot (IWGDF) conducted a systematic review which identified six studies investigating the use of electrical or electromagnetic stimulation for diabetic ulcers of the foot. The analysis of the studies provided limited evidence to suggest these therapies might be beneficial in improving outcomes. The effects on wound healing were small and in no significant differences were noted when compared to the standard of care. IWGDF 2023 Wound Healing Guideline does not currently recommend the use of electromagnetic stimulation for diabetes related full ulcer management (Chen et al., 2023).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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The FDA has not approved any electromagnetic devices specifically for the treatment of chronic wounds. Use of these devices for wound healing is an off-label indication.

For additional information search Product Code ILX at:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed September 28, 2023, 2024)

References

Aziz Z, Bell-Syer SE. Electromagnetic therapy for treating pressure ulcers. Cochrane Database Syst Rev. 2015 Sep 3;2015(9):CD002930.

Aziz Z, Cullum N. Electromagnetic therapy for treating venous leg ulcers. Cochrane Database Syst Rev. Jul 2, 2015; 7:CD002933.

Chen P, Vilorio NC, Dhatariya K, et al. Guidelines on interventions to enhance healing of foot ulcers in people with diabetes (IWGDF 2023 update). Diabetes Metab Res Rev. 2023 May 25:e3644.

ECRI Institute. Electrical Stimulation and Electromagnetic Therapy for Chronic Wounds. Plymouth Meeting (PA): ECRI Institute; 2018 Apr 27. (Custom Rapid Responses).

Kwan RL, Wong WC, Yip SL, et al. Pulsed electromagnetic field therapy promotes healing and microcirculation of chronic diabetic foot ulcers: a pilot study. Adv Skin Wound Care. 2015 May;28(5):212-9.

Kull P, Keilani M, Remer F, et al. Efficacy of pulsed electromagnetic field therapy on pain and physical function in patients with non-specific low back pain: a systematic review. Wien Med Wochenschr. 2023 Nov 24. English. Epub ahead of print.

Wang G, Zheng J, Wu H, Wu Y. Effects of electromagnetic therapy in treating patients with venous leg ulcers: An overview of systematic reviews. Int Wound J. 2024 Apr;21(4):e14852.

Policy History/Revision Information

Date	Summary of Changes
<u>TBD</u>	<u>Supporting Information</u> <ul style="list-style-type: none"><u>Updated Clinical Evidence and References sections to reflect the most current information</u><u>Archived previous policy version CS035LA.J</u>

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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