

Electromagnetic Therapy for Wounds (for Commercial Only)

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Application

This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

Coverage Rationale

The following are unproven and not medically necessary due to insufficient evidence of efficacy:

- Electromagnetic therapy for treating wounds or ulcers including but not limited to:
 - Arterial ulcers
 - Chronic pressure ulcers
 - Diabetic foot ulcers
 - Soft tissue injuries
 - Venous stasis ulcers

Definitions

Pressure Ulcer Staging (National Pressure Ulcer Advisory Panel Staging System):

- Stage III – Characterized by full-thickness loss of skin, in which fat is visible in the ulcer and granulation tissue and epibole (rolled wound edges) are often present. Slough and/or eschar may be visible. The depth of tissue damage varies by anatomical location. Undermining and tunneling may occur. Fascia, muscle, tendon, ligament, cartilage and/or bone are not exposed.
- Stage IV – Characterized by full-thickness skin and tissue loss with exposed or directly palpable fascia, muscle, tendon, ligament, cartilage or bone in the ulcer. Slough and/or eschar may be visible. Epibole (rolled edges), undermining and/or tunneling often occur. Depth varies by anatomical location.

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 the member specific benefit plan document 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.

HCPCS 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
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

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.

Clinical Evidence

Electromagnetic Therapy

There is limited evidence in the published scientific literature to support the use of electromagnetic therapy 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.

The International Working Group of the Diabetic Foot (IWGDF) published a 2016 update to the 2012 systematic review on the management of diabetic foot ulcers. Selected studies fell into several categories which included electromagnetic therapy. Heterogeneity of studies prevented pooled analysis of results. The authors reported similar conclusions as the earlier review indicating that there is little published evidence to justify the use of electromagnetic therapy for managing diabetic foot ulcers. The authors also noted that analysis of the evidence continues to present difficulties in this field as controlled studies remain few and the majority continue to be of poor methodological quality (Game et al., 2016).

In a Cochrane review, Aziz et al. (2011) assessed the effects of electromagnetic therapy (EMT) on the healing of venous leg ulcers. Three randomized controlled trials (RCTs) of variable quality involving 94 people were included in the review. All the trials compared the use of EMT with sham-EMT. 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 authors concluded that there is no high-quality evidence that electromagnetic therapy increases the rate of healing of venous leg ulcers, and further research is needed. A 2013 update and 2015 update did not identify any new trials that would change the earlier conclusions (Aziz et al., 2013, Aziz and Cullum, 2015).

In another Cochrane review, Aziz et al. (2010) assessed the effects of EMT on the healing of pressure ulcers. Two randomized controlled trials (RCTs), involving 60 participants, at unclear risk of bias were included in the 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. According to the authors, 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 included trials, both with methodological limitations and small numbers of participants. The authors state that further research is recommended. A 2012 update and 2015 update did not identify any new trials that would change the earlier conclusions (Aziz et al., 2012; Aziz and Bell-Syer, 2015).

Smith et al. (2013) summarized the evidence comparing the effectiveness and safety of treatment strategies for adults with pressure ulcers. Four randomized trials and comparative observational studies (N = 112) evaluating electromagnetic therapy were included in the review. The authors found that electromagnetic therapy was no different from sham treatment or standard care in wound-healing outcomes.

In a randomized, double-blinded study, Czyz et al. (2012) investigated the benefits of electromagnetic energy in eyelid wound healing in 57 patients who underwent upper blepharoplasty. There was no difference in patient pain rating when comparing placebo with the electromagnetic energy patch. Patients reported 6% less edema (P = .11) and 10% less ecchymosis (P = .17) with the active patch eye than in control eye. The authors concluded that the use of pulsed electromagnetic energy did not have an effect on postoperative pain, edema, or ecchymosis as rated by patients and physicians.

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.

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

Electromagnetic Therapy Devices

The Diapulse[®] device is classified by the FDA as "diathermy, shortwave, for use other than applying therapeutic deep heat" and received a device class 3 license in 1987. In 1991, the FDA notified the Diapulse Corporation that their device may only be marketed as adjunctive therapy in the palliative treatment of postoperative edema and pain in superficial soft tissue. It has not been approved by the FDA for the treatment of chronic wounds. This means the manufacturer may not market the device for wound healing although this does not prohibit physicians and other healthcare providers from providing this therapy for unapproved uses. The SofPulse[™] device is also classified under "diathermy, shortwave, for use other than applying therapeutic deep heat" and received a device class 3 license in 1996. Available at:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=890.5290>. (Accessed March 28, 2023)

The Provant[®] Wound Closure System utilizes the Regenesys Model 42, classified by the FDA as a short-wave diathermy device. It received 510(k) clearance in October 1997 for use in the palliative treatment of postoperative pain and edema in superficial soft tissue. According to the FDA, this device applies electromagnetic energy to the body and is substantially equivalent to the SofPulse device. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf13/K131979.pdf. (Accessed March 28, 2023)

References

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Czyz CN, Foster JA, Lam VB, et al. Efficacy of pulsed electromagnetic energy in postoperative recovery from blepharoplasty. *Dermatol Surg.* 2012 Mar;38(3):445-50.

Game FL, Apelqvist J, Attinger C, et al.; International Working Group on the Diabetic Foot. Effectiveness of interventions to enhance healing of chronic ulcers of the foot in diabetes: a systematic review. *Diabetes Metab Res Rev.* 2016a Jan;32 Suppl 1:154-68.

Smith ME, Totten A, Hickam DH, et al. Pressure ulcer treatment strategies: a systematic comparative effectiveness review. *Ann Intern Med.* 2013 Jul 2;159(1):39-50.

Policy History/Revision Information

Date	Summary of Changes
09/01/2023	<p>Title Change</p> <ul style="list-style-type: none">Previously titled <i>Electrical Stimulation and Electromagnetic Therapy for Wounds</i> <p>Application</p> <ul style="list-style-type: none">Removed language indicating this Medical Policy applies to UnitedHealthcare Individual Exchange benefit plans; refer to the Medical Policy titled <i>Electromagnetic Therapy for Wounds (for Individual Exchange Only)</i> <p>Coverage Rationale</p> <ul style="list-style-type: none">Removed language indicating:<ul style="list-style-type: none">Electrical stimulation is proven and medically necessary for treating Stage III or IV pressure ulcers that have failed to demonstrate measurable signs of healing with 30 days of conventional treatment which includes all of the following:<ul style="list-style-type: none">Application of dressings to maintain a moist wound environmentAppropriate turning and positioningDebridement of necrotic tissue, if presentEvaluation of and provision for adequate nutritional statusMoisture and incontinence managementUse of a pressure-reducing support surfaceElectrical stimulation is unproven and not medically necessary for treating all other wounds or ulcers due to insufficient evidence of efficacy, including but not limited to:<ul style="list-style-type: none">Diabetic ulcersVenous stasis ulcers <p>Definitions</p> <ul style="list-style-type: none">Removed definition of “Measurable Signs of Healing” <p>Applicable Codes</p> <ul style="list-style-type: none">Removed HCPCS codes G0281 and G0282 <p>Supporting Information</p> <ul style="list-style-type: none">Updated <i>Description of Services, Clinical Evidence, FDA, and References</i> sections to reflect the most current informationRemoved <i>Documentation Requirements</i> sectionArchived previous policy version 2023T0527O

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual[®] criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.