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

Last Approval: 8/10/2022
Next Review Due By: August 2023

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

Electrical stimulation is the application of electrical current through electrodes placed on the skin near the wound and to the saline-moistened gauze placed over the wound. The saline provides a conductive medium that allows electric current to pass directly through the wound. The intent of electrical stimulation is to facilitate wound healing by promoting angiogenesis, collagen synthesis, proliferation of fibroblasts, and migration of epithelial cells. The types of electrical stimulation and devices can be categorized into 4 groups based on the type of current, low-intensity direct current (LIDC), high-voltage pulsed current (HVPC), alternating current (AC), and transcutaneous electrical nerve stimulation (TENS) (CMS, 2004 & 1996).

Electromagnetic therapy (EMT) is the application of electromagnetic fields to the wound area, rather than direct application of electrical current. This therapy is also referred to as pulsed electromagnetic induction (PEMI), pulsed electromagnetic field (PEMF), and pulsed EMT. It is used as an adjunct to standard therapy and is not a substitute for standard wound therapy (CMS, 2004 & 1996).

Standard wound care includes optimization of nutritional status; debridement by any means to remove devitalized tissue; maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings; and necessary treatment to resolve any infection that may be present. Standard wound care based on the specific type of wound includes frequent repositioning of a patient with pressure ulcers (usually every 2 hours); offloading of pressure; and good glucose control for diabetic ulcers, establishment of adequate circulation for arterial ulcers, and the use of a compression system for patients with venous ulcers (CMS, 2004 & 1996).

According to CMS National Coverage Determination 270.1, “the use of electrostimulation (ES) and electromagnetic therapy for the treatment of wounds are considered adjunctive therapies and will only be covered for chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers. Chronic ulcers are defined as ulcers that have not healed within 30 days of occurrence. ES or electromagnetic therapy will be covered only after appropriate standard wound therapy has been tried for at least 30 days and there are no measurable signs of improved healing. This 30-day period may begin while the wound is acute. Measurable signs of improved healing include: a decrease in wound size (either surface area or volume), decrease in amount of exudates, and decrease in amount of necrotic tissue. ES or electromagnetic therapy must be discontinued when the wound demonstrates 100% epitheliliazed wound bed. ES and electromagnetic therapy services can only be covered when performed by a physician, physical therapist, or incident to a physician service. Evaluation of the wound is an integral part of wound therapy. When a physician, physical therapist, or a clinician incident to a physician, performs ES or electromagnetic therapy, the practitioner must evaluate the wound and contact the treating physician if the wound worsens. If ES or electromagnetic therapy is being used, wounds must be evaluated at least monthly by the treating physician.” (CMS, 2004 & 1996).

Regulatory Status

The Food and Drug Administration (FDA) has not approved any electrical stimulation or electromagnetic devices for the treatment of chronic wounds. Use of these devices for wound healing is considered an off-label indication.

COVERAGE POLICY

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

Electrical stimulation performed in any setting **is considered experimental, investigational and unproven** for wound care including venous stasis ulcers, arterial ulcers, diabetic foot ulcers, and chronic pressure sores due to insufficient evidence in the peer reviewed medical literature.

Electromagnetic therapy performed in any setting **is experimental, investigational and unproven** for wound care including venous stasis ulcers, arterial ulcers, diabetic foot ulcers, chronic pressure sores 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)

There is insufficient evidence from well-designed randomized controlled trials (RCTs) that ES or electromagnetic stimulation is safe and effective as an adjunct to standard wound care or increase the healing rate of chronic dermal or cutaneous wounds beyond that provided by standard treatment. Some small RCTs on ES have reported improvements in some intermediate outcomes, such as decrease in wound size and/or the velocity of wound healing. However, these studies have not demonstrated consistent improvements on the more important clinical outcomes of complete healing and the time to complete healing. There were substantial methodological flaws in the available studies, which make it difficult to define the magnitude of treatment effects and to determine what types of wounds are most likely to benefit from electrical stimulation. There is also insufficient evidence to determine the type of device or form of electrical current for use in wound healing (Barnes et al. 2014).

Arora et al. performed a *Cochrane Review* to determine the effects (benefits and harms) of ES for treating pressure ulcers. 20 studies with 913 participants were included in the review and the age of participants ranged from 26 to 83 years; 50% were male. ES was administered for a median interquartile range duration of 5 (4 to 8) hours per week. The chronicity of the pressure ulcers was variable, ranging from a mean of 4 days to more than 12 months. Most of the pressure ulcers were on the sacral and coccygeal region (30%), and most were stage III (45%). Half the studies were at risk of performance and detection bias, and 25% were at risk of attrition and selective reporting bias. Overall, the GRADE assessment of the certainty of evidence for outcomes was moderate to very low. The results of this review indicated the following conclusions (Arora et al. 2020; Aziz and Cullum 2015; Aziz et al. 2013).

- ES probably increases the proportion of pressure ulcers healed compared with no ES [risk ratio (RR) 1.99, 95% confidence interval (CI) 1.39 to 2.85; I^2 = 0%; 11 studies, 501 participants (512 pressure ulcers)]. We downgraded the evidence to moderate certainty due to risk of bias.
- It is uncertain whether ES decreases pressure ulcer severity on a composite measure compared with no ES (mean difference (MD) -2.43, 95% CI -6.14 to 1.28; 1 study, 15 participants (15 pressure ulcers) and whether ES decreases the surface area of pressure ulcers when compared with no ES (12 studies; 494 participants; 505 pressure ulcers). Data for the surface area of pressure ulcers were not pooled because there was considerable statistical heterogeneity between studies (I^2 = 96%) but the point estimates for the MD of each study ranged from -0.90 cm^2 to 10.37 cm^2. We downgraded the evidence to very low certainty due to risk of bias, inconsistency and imprecision.
- It is uncertain whether ES decreases the time to complete healing of pressure ulcers compared with no ES [hazard ratio (HR) 1.06, 95% CI 0.47 to 2.41; I^2 = 0%; 2 studies, 55 participants (55 pressure ulcers)]. We downgraded the evidence to very low certainty due to risk of bias, indirectness and imprecision.

- ES may be associated with an excess of, or difference in, adverse events [13 studies; 586 participants (602 pressure ulcers)]. Data for adverse events were not pooled but the types of reported adverse events included skin redness, itchy skin, dizziness and delusions, deterioration of the pressure ulcer, limb amputation, and occasionally death. We downgraded the evidence to low certainty due to risk of selection and attrition bias and imprecision.
- ES probably increases the rate of pressure ulcer healing compared with no ES [MD 4.59% per week, 95% CI 3.49 to 5.69; I^2 = 25%; 12 studies, 561 participants (613 pressure ulcers)]. We downgraded the evidence to moderate certainty due to risk of bias. We did not find any studies that looked at quality of life, depression, or consumers' perception of treatment effectiveness.

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 *Cochrane 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 *Cochrane Review* to assess the effects of EMT on the healing of pressure ulcers. Two randomised controlled trials (RCTs), 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 included trials, 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 EMT (Qaseem et al., 2015).

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes – None.

HCPCS 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

ICD-10 Codes – Any / All.

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

8/10/2022 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).

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: National coverage determination (NCD) – electrical stimulation (ES) electromagnetic therapy treatment of wounds (270.1). Available from CMS. Effective July 1, 2004. Accessed June 2022.
2. Centers for Medicare and Medicaid Services (CMS). National coverage analysis (NCA): Electrostimulation for wounds (CAG-00068N). Available from CMS. Published April 1996. Accessed June 2022.
3. United States Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH). Summary of safety and effectiveness data. Available from FDA. Updated February 3, 2022. Accessed June 2022.

Peer Reviewed Publications

1. Barnes R, Shahin Y, Gohil R, Chetter I. Electrical stimulation vs. standard care for chronic ulcer healing: A systematic review and meta-analysis of randomised controlled trials. Eur J Clin Invest. 2014 Apr;44(4):429-40. doi: 10.1111/eci.12244. Accessed July 2022.
2. Arora M, Harvey LA, Glinsky JV, Nier L, Lavrencic L, Kifley A, et al. Electrical stimulation for treating pressure ulcers. Cochrane Database Syst Rev. 2020 Jan 22;1(1):CD012196. doi: 10.1002/14651858.CD012196.pub2. Accessed July 2022.
3. Aziz Z, Cullum N, Flemming K. Electromagnetic therapy for treating venous leg ulcers. Cochrane Database Syst Rev. 2013 Feb 28;(2):CD002933. doi: 10.1002/14651858.CD002933.pub5. Accessed July 2022.
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National and Specialty Organizations

1. Qaseem A, Humphrey LL, Forciea MA, Clinical Guidelines Committee of the American College of Physicians, et al. Treatment of pressure ulcers: A clinical practice guideline from the American College of Physicians. Ann Intern Med. 2015 Mar 3;162(5):370-9. doi: 10.7326/M14-1568. Accessed July 2022.

Other Peer Reviewed and Professional Organization Publications (used in the development of this policy)

1. European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and treatment of pressure ulcers/injuries: Quick reference guide. Available here. Published 2019. Accessed July 2022.
2. Game FL, Apelqvist J, Attinger C, Hartemann A, Hinchliffe RJ, International Working Group on the Diabetic Foot, et al. Effectiveness of interventions to enhance healing of chronic ulcers of the foot in diabetes: A systematic review. Diabetes Metab Res Rev. 2016 Jan;32 Suppl 1:154-68. doi: 10.1002/dmrr.2707. PMID: 26344936. Accessed July 2022.
3. Lala D, Spaulding SJ, Burke SM, Houghton PE. Electrical stimulation therapy for the treatment of pressure ulcers in individuals with spinal cord injury: A systematic review and meta-analysis. Int Wound J. 2016 Dec;13(6):1214-1226. doi: 10.1111/iwj.12446. Accessed July 2022.
4. Liu L, Moody J, Gall A. A quantitative, pooled analysis and systematic review of controlled trials on the impact of electrical stimulation settings and placement on pressure ulcer healing rates in persons with spinal cord injuries. Ostomy Wound Manage. 2016 Jul;62(7):16-34. PMID: 27428563. Available from PubMed. Accessed July 2022.
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7. Polak A, Kloth LC, Blaszczak E, et al. The efficacy of pressure ulcer treatment with cathodal and cathodal-anodal highvoltage monophasic pulsed current: A prospective, randomized, controlled clinical trial. Phys Ther. 2017 Aug 1;97(8):777-789. doi: 10.1093/ptj/pzx052. PMID: 28789467. Accessed July 2022.
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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.*