

Medical Policy Manual

Durable Medical Equipment, Policy No. 83.13

Electromagnetic Therapy

Effective: January 1, 2025

Next Review: October 2025 Last Review: December 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Electromagnetic therapy (EMT), sometimes called pulsed electromagnetic field therapy (PEMF), involves the application of electromagnetic fields to the body and has been proposed for the treatment of various conditions including pain and wound healing.

MEDICAL POLICY CRITERIA

Note: Electrical stimulation as a treatment of pain, other musculoskeletal conditions, bone growth, and wounds are considered in separate plan Medical Policies (see Cross References).

Electromagnetic therapy, with or without concurrent optical stimulation, for any indication including, but not limited to the treatment of pain or as an aid to wound healing, is considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Interferential Current Stimulation, DME, Policy No. 83.07

- 2. Electrical Stimulation for the Treatment of Wounds, DME, Policy No. 83.09
- 3. Electrical Stimulation for the Treatment of Arthritis, DME, Policy No. 83.10
- 4. Electrical Bone Growth Stimulators (Osteogenic Stimulation), DME, Policy No. 83.11
- 5. Non-Contact Ultrasound Treatments for Wounds, Medicine, Policy No. 131
- 6. Transcutaneous Electrical Modulation Pain Reprocessing, Medicine, Policy No. 143

BACKGROUND

Electromagnetic therapy (EMT), also known as electromagnetism, bioelectricity, magneto biology, magnetic healing, electromagnetic field therapy and magnetic field therapy, involves the application of electromagnetic fields to the body. EMT has been proposed for the treatment of various conditions including pain and wound healing. Unlike other forms of electrotherapy, EMT does not use direct electrical effects or radiation, but induces a field effect. Some devices deliver either a continuous or a pulsed electromagnetic field (PEMF). A number of devices, some of which are discussed below, have been constructed to deliver a pulsed electromagnetic field (PEMF) in the radio frequency band. The frequency of short-wavelength radio waves ranges from 10 to 100 MHz and the frequency commonly used in EMT is 27.12 MHz. An advantage of PEMF is reported to be that the short duration of the pulses protects the tissues against potential damage from heat generated by continuous fields. The mechanisms by which PEMT may impact biological processes to improve health is not entirely understood.

REGULATORY STATUS

In 2015, the Food and Drug Administration (FDA) issued an order to reclassify shortwave diathermy (SWD) devices intended for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue by means other than generation of deep heat within body tissues from class III to class II and to rename the technology "nonthermal shortwave therapy (SWT)."[1]

Examples of nonthermal SWT devices that apply pulsed electromagnetic energy that have received 510(k) clearance for adjunctive use in the palliative treatment of post-operative pain and edema in superficial soft tissue include:

- The SofPulse[™] (also Torino II, 912-M10, and Roma3[™], Ivivi Health Sciences); FDA Product Code ILX, K070541
- The Zeiobi (Ivivi Health Sciences); FDA product code ILX, K121338

In 2017, the ActiPatch® (BioElectronics), a nonthermal SWT device used for the application of electromagnetic energy to non-thermally treat pain, received 501(k) clearance from the FDA for use as adjunctive treatment of plantar fasciitis of the heel and osteoarthritis of the knee. In 2020, the ActiPatch was cleared for marketing as an adjuvant treatment for musculoskeletal pain; FDA product code PQY, K192234.

The Magnetofield® (F&B International, Italy) and Elettronica Pagani (Energy Plus Roland Series, Italy) devices provide pulsed electromagnetic field therapy. They are currently marketed in Europe.

The Axon Therapy Device (NeuraLace Medical, Inc), a transcutaneous electrical nerve stimulator, received 510(k) approval in 2021.

The Concurrent Optical and Magnetic Stimulation (COMS®) One Therapy System (Piomic) received an Investigational Device Exemption from the FDA in 2022. The COMS® One Therapy System is intended to facilitate healing of wounds that have not responded to 30 days of standard wound care.

EVIDENCE SUMMARY

ELECROMAGNETIC THERAPY FOR THE TREATMENT OF PAIN ASSOCIATED WITH ARTHRITIS

The principal outcomes associated with treatment of pain due to any cause may include: relief of pain, improved functional level, and return to work. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Treatment with an electromagnetic therapy (EMT) device must also be evaluated in general groups of patients against the existing standard of care for the condition being treated. For example, in patients with pain symptoms, treatment with an EMT device should be compared with other forms of conservative treatment for pain. Therefore, data from adequately powered, blinded, randomized controlled trials (RCT) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from an electrical stimulation device provides a significant advantage over the placebo over an extended period of time.

Systematic Reviews

Tong (2022) conducted a systematic review of 11 RCTs in which patients with osteoarthritis received pulsed electromagnetic fields or control treatment.^[2] Six studies had a sham group. and five studies used other treatments including hot packs, transcutaneous electrical nerve stimulation (TENS), physiotherapy, and ultrasound. Many of the trials described below were included in the analysis, along with some additional studies. Risk of bias was high in six studies, moderate in two studies, and low in three studies. The main outcomes measured the efficacy of pulsed electromagnetic field stimulation on osteoarthritis-related soreness, stiffness, and physical function assessed by visual analog scale (VAS) and/or Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores. Compared to controls, pulsed electromagnetic field stimulation significantly reduced pain (standardized mean difference [SMD], 0.71; 95% confidence interval [CI], 0.08 to 1.34; p=0.03; I^2 =93%). There were also significant differences in stiffness (SMD, 1.34; 95% CI, 0.45 to 2.23; p=0.003; I²=99%) and physical function (SMD, 1.52; 95% CI, 0.49 to 2.55; p=0.004; I²=95%) with pulsed electromagnetic field stimulation. All three outcomes were significantly better with pulsed electromagnetic field stimulation compared to sham treatment but not compared to other treatments. Limitations of the analysis included the small number of studies, high heterogeneity, and the combined analysis of sham and other interventions.

Vigano (2021) published a systematic review of 13 studies evaluating the effect of electromagnetic field treatment on patients with knee osteoarthritis. An overall reduction in pain score was seen after treatment whereas no improvement in activity scores was seen. When separating the analysis by control group (placebo v. alternative treatments), there were differences in analytical outcomes within the review. When comparing electromagnetic field treatment to alternative treatments (e.g., physical therapy), no differences in pain or activity scores were seen. Only when comparing the treatment to placebo were any differences present and those differences went away as the follow-up time increased. The authors concluded that there may be short term benefit to electromagnetic field therapy but it is not superior to alternative treatments such as physical therapy. Another systematic review was

published by Markovic which included similar studies as the review by Vigano and had similar findings of potential short term benefits without any strong evidence of durable outcomes.^[4]

Yang (2020) published a systematic review (SR) evaluating the effects of pulsed electromagnetic field (PEMF) therapy on pain, stiffness, physical function, and quality of life in patients with osteoarthritis. The meta-analysis included 15 small, sham- or placebo-controlled studies published between 1993 and 2016 (N=985). Overall, the quality of evidence was low or very low; only two studies were deemed to be at low risk of bias. The primary outcome was the standardized mean difference which is defined as the treatment effect in the PEMF group minus the treatment effect in the placebo group divided by the pooled standard deviation. A significant beneficial treatment effect was found for pain (SMD, 1.06; 95% CI, 0.61 to 1.51), stiffness (SMD, 0.37; 95% CI, 0.07 to 0.67), and physical function (SMD, 0.46; 95% CI, 0.14 to 0.78), but not quality of life (SMD, 1.49; 95% CI, -0.06 to 3.04). Only pain outcomes were considered clinically significant. Studies were limited to the short-term effects of PEMF therapy, with study follow-up durations ranging from 10 days to 12 weeks.

A SR with meta-analysis evaluating the efficacy of PEMF therapy on patients with knee osteoarthritis was published by Chen (2019). [6] Eight randomized controlled trials (RCTs) comparing classical PEMF to placebo treatment (N=421) were included. Overall quality assessment indicated that all included studies had a low or moderate risk of bias. PEMF therapy improved physical function (weighted mean difference; WMD = -5.28, 95% CI -9.45 to -1.11, p = 0.01), but no significant improvement was found in the reduction of Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) total score, WOMAC pain score, WOMAC stiffness score, or visual analog scale pain score. The authors concluded that additional randomized controlled trials are needed to confirm these findings and to determine the optimal parameters and treatment regimen for pulsed electromagnetic field therapy in knee osteoarthritis.

In 2017, an Agency for Healthcare Research and Quality SR by Newberry assessed options for treatment of osteoarthritis of the knee. Three studies were identified that compared PEMF to sham, all of which were short-term studies; no RCTs that assessed medium- or long-term outcomes were identified. A pooled analysis of these three RCTs found a statistically nonsignificant benefit of PEMF on short-term pain. The SR concluded that evidence is insufficient to assess the effects of PEMF on short term function or other outcomes. A number of limitations were reported for the included studies such as a lack of blinding, inability to ascertain allocation concealment, and lack of intent-to-treat analysis.

In 2013, Negm published results from SR with meta-analysis, which included seven small sham controlled RCTs with a total of 459 patients, which examined PES or PEMF for the treatment of knee osteoarthritis. [8] The trials were published between 1994 and 2011, five were conducted outside of the United States, and only one was considered to be at low risk of bias. There was no significant difference between the active and sham groups for the outcome of pain. Physical function was significantly higher with PES/PEMF, with a standardized mean difference of 0.22. The internal validity of the included studies is limited due to a number of factors. There is a high risk of bias and inconsistent results reported. The studies all had small sample sizes, leading to imprecise estimates of treatment effect.

Randomized Controlled Trials

Yabroudi (2024) evaluated the effects of pulsed electromagnetic field therapy combined with progressive resistance exercise (PRE) in improving physical function and pain in patients with

knee osteoarthritis.^[9] Patients were randomized to receive either 24 sessions of pulsed electromagnetic field therapy plus PRE (n=17) or PRE alone (n=17). Compared to baseline assessments, both groups scored higher on post-treatment, three-month, and six-month follow-up scores of Knee Injury and Osteoarthritis Outcome Score (KOOS) and Numeric Pain Rating Scale (NPRS). Both groups were also able to complete the 5-times chair stand test and walking speed test faster at post-treatment timepoints compared to baseline. However, these outcomes were not significantly different between the pulsed electromagnetic field therapy plus PRE or PRE alone groups.

de Paula Gomes (2020) conducted a prospective, randomized, sham-controlled trial evaluating the effects of an exercise program alone or combined with electrophysical modalities in patients with knee osteoarthritis (N=100). Patients were equally allocated into five groups (n=20): exercise, exercise + sham, exercise + interferential current therapy (ICT), exercise + pulsed shortwave diathermy therapy (SDT), and exercise + photobiomodulation. Patients received treatment three times weekly for eight weeks. A significant improvement in Western Ontario and McMaster Universities (WOMAC) function and pain scores was observed in the exercise only group compared to all other groups, including SDT. The addition of ICT, SDT, or photobiomodulation did not result in any clinically meaningful benefits. No long-term follow-up assessments were performed after the eight- week treatment period and use of analgesics was not controlled in the study.

Khooshidehet (2017) reported on an RCT of 72 women treated with PEMF therapy or sham PEMF following Cesarean section. [11] The primary outcome was a reduction of pain during recovery, which was assessed using a visual analog scale (VAS) at regular intervals for seven 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, two hours after surgery, PEMF patients had a mean VAS score of 53 compared with that of sham patients (VAS score, 63; p=0.01). 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=0.01). 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=0.002). 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<0.001). 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=0.58).

Bagnato (2016) reported a double-blind, sham-controlled trial of nightly treatment (12 hours) with a wearable ActiPatch®, an electromagnetic device. [12] Sixty-six patients with osteoarthritis were randomized and 60 completed the trial. Patients in the treatment group showed statistically significant improvements in pain, WOMAC scores, and SF-36 physical scores. The authors concluded the study was limited in size and future larger studies for a longer duration are needed.

In 2013, Nelson published results from a pilot RCT regarding PEMF therapy in 34 patients with osteoarthritis.^[13] In addition to having knee pain with confirmed articular cartilage loss and an initial VAS score of four or more, only patients who had at least two hours of daily standing activity in a physical occupation were included in the study. Patients were instructed to use the electromagnetic device for 15 min twice daily, and the total number of sessions used was recorded by the device. An average 80 of 84 possible sessions were recorded. Patients were

asked to self-report the maximum daily VAS pain score on a 10 cm line for weeks one and two, and then for weeks five and six. By the end of the study, three active and seven sham patients had dropped out of the study due to a lack of perceived benefit. At baseline, there was no significant difference in VAS between the active (6.8) and sham (7.1) treatment groups. Using intent-to-treat analysis with last observation carried forward, the average decrease in VAS was 2.7 in the active treatment group (statistically significant) and 1.5 in the sham group (not statistically significant). By the end of the study, the maximum VAS decreased by 39% in patients receiving the active treatment and 15% in the sham group. The difference between groups (4.19 vs. 6.11) was statistically and clinically significant.

In 2010 Ozguclu published results from a double-blind RCT which investigated the effect of PEMF in 40 patients with knee osteoarthritis.^[14] Patients with an average pain intensity of 40 or more on a 100-mm visual analog scale (VAS) were randomly assigned to receive PEMF or sham PEMF in addition to their physical therapy. Sessions included 20-min hot pack, 5-min ultrasound, and 30-min PEMF or sham and were provided five times per week for two weeks, along with isometric knee exercises performed at home. After two weeks, both groups showed improvement in pain and functional scores; there were no significant differences between the two groups.

Section Summary

The evidence evaluating the added benefit of electromagnetic therapy in the treatment of pain associated with arthritis includes three SRs and several small RCTs. The pooled analyses in the SRs have found no significant reduction of pain with the use electromagnetic therapy over placebo or sham controls. Additional RCTs with larger sample size and longer duration are needed to determine the added health benefit of this technology on pain associated with arthritis.

ELECTROMAGNETIC THERAPY FOR THE TREATMENT OF WOUNDS

The principal outcomes associated with the treatment of wounds, particularly chronic wounds, are complete wound closure, improvement in the rate or quality of healing (such as the minimization of scarring), treatment of infection, and patient-centered outcomes such as improvements in function or mobility, and minimization of pain. Outcomes relating to the use of a device delivering electromagnetic therapy for the treatment of wounds are best understood when comparing use of either type of device to a sham device among patients with similar wound type (i.e., burn or chronic diabetic ulcer), who are receiving standardized wound care regimens. Therefore, data from adequately powered, blinded, randomized sham-controlled trials are required to control for bias and determine whether any treatment effect from electromagnetic therapy devices provides a significant advantage over standard wound care.

Systematic Reviews and Technology Assessments

Zheng (2022) conducted a systematic review and meta-analysis comparing electrostimulation to standard of care or placebo in 352 patients with diabetes-related ulcers. [16] Electrostimulation improved ulcer area reduction and healing rates; however, four studies were considered at high risk of bias, and there was high heterogeneity limiting applicability of these findings. Individual trial sample sizes were quite small, and additional properly designed RCTs are necessary to establish electrostimulation efficacy in patients with diabetes-related ulcers.

Aziz and Bell (2015) published an update to a previous Cochrane SR that assessed the effects EMT versus sham EMT on the healing of pressure ulcers. [17] Two RCTS (as in the previous review, N=60) at unclear risk of bias were included in the original review. There were no significant differences in complete wound healing between the groups. One RCT identified a significant reduction in wound surface area with EMT treatment. The authors concluded there was no strong evidence to support EMT for the treatment of pressure ulcers and the one study that showed EMT effective in the treatment of pressure ulcers was small. Both RCTs had methodological limitations.

Aziz and Cullum (2015) published a Cochrane SR that assessed the effects of EMT on the healing of venous leg ulcers. ^[18] Three randomized controlled trials were included were included in the review comprising 94 people. All trials included in the review compared the use of EMT with sham-EMT; however, due to heterogeneity a meta-analysis could not be completed. Two of the trials included in the review reported a significant finding on healing with the EMT group. The first study included 44 participants and reported that significantly more ulcers healed in the EMT group when compared to the sham-EMT group; however, the authors reported there were a number of participants that were lost to follow-up making it challenging to determine significance in wound healing. The second study comprised 31 participants and reported a significantly greater reduction in ulcer size in the EMT group; however, the authors reported this result was likely influenced by the differences in prognostic profiles of the treatment groups. The third study included in the review found no significant difference in healing. Based on these findings, the authors concluded that it is unclear whether EMT therapy influences the rate of healing of venous leg ulcers; therefore, further research is needed to determine the efficacy of EMT treatment on wounds.

The Agency for Healthcare Research and Quality (AHRQ) (2013) published a comparative effectiveness review to evaluate the optimal treatment strategy for pressure ulcers. [19] Although the group considers complete wound healing to be the primary outcome of interest, wound improvement was also considered, as "it represents a necessary intermediate step toward the principal outcome of complete wound healing...(and) the likelihood of complete wound healing is lower for larger or higher staged ulcers." The strength of evidence for electromagnetic therapy in acceleration of healing and wound improvement was low. Low was defined as, "low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate." Across the four studies evaluating this technology, wound improvement for stage II, III, or IV pressure ulcers was similar to sham treatment. However, the agency did note that while electromagnetic therapy showed a tendency toward wound improvement, consistent effectiveness in complete wound healing was not demonstrated.

Randomized Controlled Trials

Tassone (2023) published a double-blind RCT that assessed the effectiveness of pulsed electromagnetic therapy on painful diabetic distal symmetric peripheral neuropathy (DSPN).^[20] 182 subjects with diabetes and confirmed DSPN were randomized to either active pulsed electromagnetic field therapy treatment or nonactive sham and instructed to treat their feet for 30 minutes, twice daily and report daily pain scores. Patients in the active treatment group, who did not have issues with placement of treatment equipment, experienced a clinically significant 30% reduction in pain from baseline compared to sham, though this result was not statistically significant.

In the RCT by Khooshidehet (2017) in women treated with PEMF therapy or sham PEMF following Cesarean section summarized above, secondary outcomes included wound healing.^[11] Unlike other outcomes, wound healing was assessed 10 days after surgery, rather than seven. 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=0.04). 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=0.58).

Section Summary

The evidence on the use of electromagnetic therapy includes two systematic reviews of RCTs (one on pressure ulcers and the other on leg ulcers), a comparative effectiveness review, 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.

CONCURRENT OPTICAL AND MAGNETIC STIMULATION FOR THE TREATMENT OF WOUNDS

Nonrandomized Studies

Reinboldt-Jockenhöfer (2022) published a prospective clinical trial that evaluated the safety and efficacy of concurrent optical and magnetic stimulation (COMS) as an adjunct to standard of care (SOC) for patients with hard-to-heal lower extremity wounds. [21] Wounds included venous, arterial, and mixed leg ulcers that were between 1 and 50 cm² and had not responded to standard wound care in 30 days. Wound healing was assessed during SOC treatment for four weeks to provide a baseline control. COMS treatment was added as an adjunctive treatment to SOC for eight weeks and was administered two to three times per week for 16 minutes. The study found that COMS was safe, with most adverse events being mild or moderate and unrelated to the treatment (n=37). 30 patients were analyzed for secondary endpoints including change in wound area and volume, pain level, and quality of life. Wound healing accelerated during the first four weeks of COMS treatment compared to baseline (p=0.041). The rates of near-complete and complete wound closure were 60% and 43% at 12 weeks. Pain reduction across the treatment group was statistically significant (p≤0.002). The Wound-Quality of Life score improved by 24% during the study (p=0.001). This study is limited by small sample size, lack of a parallel control group, and lack of long-term follow-up.

ELECTROMAGNETIC THERAPY FOR OTHER CONDITIONS

de Pedro Negri (2022) published a review on the efficacy of magnetic therapy in the treatment of chronic pelvic pain across five clinical trials including 278 patients. [22] Although the authors concluded there may be a net positive benefit in pain reduction, there is significant heterogeneity in treatment techniques, treatment duration, and number of treatment sessions and results should be interpreted with caution.

Vinolo-Gil (2022) published a systematic review on the effects of peripheral electromagnetic fields on spasticity including ten clinical trials.^[23] The outcomes across the different studies included improvements in stretch reflex threshold, self-questionnaire about difficulties related to spasticity, clinical spasticity score, performance scale, Ashworth scale, spastic tone,

Hmax/Mmax Ratio and active and passive dorsal flexion. The authors reported positive results on spasticity in 80% of the studies however cautioned the interpretation of the results due to significant heterogeneity and a small number of included articles.

A 2013 Cochrane SR published by Kroeling evaluated the short, intermediate, and long-term effects of electrotherapy on pain, function, disability, patient satisfaction, global perceived effect, and quality of life from 20 RCTs (N=1239) in adults with neck pain. Across the studies, very low quality evidence showed that PEMF and repetitive magnetic stimulation (rMS) were more effective than placebo. The authors concluded that because the evidence is of very low quality, the estimate of the effect is not clear and that funding bias should be considered, especially in PEMF studies. Additional RCTs with larger patient samples, more precise standardization, and detailed treatment characteristics are needed.

Weintraub (2009) published the results of a multi-site RCT in 225 patients with painful diabetic peripheral neuropathy (DPN) randomized to receive either PEMF or placebo for three months. While there was a trend toward reductions in DPN perceived symptoms favoring the PEMF group (44% vs 31%; p=0.04), no significant differences between PEMF and sham groups in the Neuropathy Pain Scale or visual analogue pain scale were observed. In the subset of patients undergoing serial biopsy (n=27), 39% of the treatment group had an increase in nerve fiber density, which was not observed in the sham group.

Evidence in the published peer-reviewed scientific literature evaluating PEMF therapy for conditions other than pain associated with arthritis or the treatment of wounds consists mainly of case series and a few RCTs. PEMF has been used for the treatment of numerous other conditions, such as cervical disk herniation, [25] metabolic syndrome, [26] soft tissue injuries, [27] multiple sclerosis, nonspecific low back pain, [28] fibromyalgia, [29] and for various other conditions related to pain. Treatment groups are not consistently observed to have improved health outcomes over sham or control groups. The ability to draw conclusions regarding the added benefit of PEMF on health outcomes is limited by studies with small sample sizes, high risk of bias, and inconsistent treatment or outcome parameters across studies.

PRACTICE GUIDELINE SUMMARY

AMERICAN COLLEGE OF RHEUMATOLOGY

In 2019, the American College of Rheumatology (ACR) released guidelines for the management of osteoarthritis of the hand, hip, and knee. [30] The guidelines do not mention pulsed electrical or electromagnetic stimulation.

OSTEOARTHRITIS RESEARCH SOCIETY INTERNATIONAL

In 2019, the Osteoarthritis Research Society International published updated evidence-based consensus guidelines for the nonsurgical management of knee, hip, and polyarticular osteoarthritis.^[31] Sixty treatment modalities were evaluated for 43 patient groups: knee-only, hip, and multijoint osteoarthritis. Electromagnetic therapy was considered "strongly recommended against" for all groups due to low quality evidence and an implausible biological mechanism.

THE AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

In 2021, the American Academy of Orthopaedic Surgeons published updated guidelines on the treatment of osteoarthritis of the knee. [32] The guidelines noted that there was only one study

"that examined the use of a wearable pulsed electromagnetic field device for pain management in subjects with knee osteoarthritis." The strength of recommendation was downgraded to "limited" from inconclusive since there is only this single "moderate" quality study recommending for or against the intervention. In 2023, the American Academy of Orthopaedic Surgeons (AAOS) published guidelines on the management of osteoarthritis of the hip.^[33] Use of electromagnetic therapy for the treatment of osteoarthritis of the hip were not addressed.

ASSOCIATION FOR THE ADVANCEMENT OF WOUND CARE

The Association for the Advancement of Wound Care published guidelines (2015) on the care of venous ulcers that included electrostimulation and electromagnetic stimulation as treatment modalities.^[34] These recommendations were with "moderate" strength of recommendation. The AAWC also published a guideline (2010) for the care of pressure ulcers.^[35] The guideline did not address electromagnetic therapy.

WOUND HEALING SOCIETY

Gould (2016) published updated 2015 guidelines for pressure ulcers.^[36] The guidelines state that electrical stimulation may provide healing for pressure ulcers that fail conservative treatments. It is not known what types of electrical stimulation will provide benefit, nor has it been determined which wounds are most likely to respond.

SUMMARY

There is not enough research to show that electromagnetic therapy improves health outcomes for any indication, including the treatment of pain or wound healing. No clinical guidelines based on research recommend electromagnetic therapy for any indication. Therefore, the use of electromagnetic therapy is considered investigational for all indications, including the treatment of pain or wound healing.

REFERENCES

- 1. Federal Register: Physical Medicine Devices. [cited 10/30/2024]. 'Available from:' https://www.federalregister.gov/documents/2015/10/13/2015-25923/physical-medicine-devices-reclassification-of-shortwave-diathermy-for-all-other-uses-henceforth-to.
- 2. Tong J, Chen Z, Sun G, et al. The Efficacy of Pulsed Electromagnetic Fields on Pain, Stiffness, and Physical Function in Osteoarthritis: A Systematic Review and Meta-Analysis. *Pain research & management.* 2022;2022:9939891. PMID: 35586276
- 3. Viganò M, Perucca Orfei C, Ragni E, et al. Pain and Functional Scores in Patients Affected by Knee OA after Treatment with Pulsed Electromagnetic and Magnetic Fields: A Meta-Analysis. *Cartilage*. 2021;13(1_suppl):1749s-60s. PMID: 32508140
- 4. Markovic L, Wagner B, Crevenna R. Effects of pulsed electromagnetic field therapy on outcomes associated with osteoarthritis: A systematic review of systematic reviews. *Wien Klin Wochenschr.* 2022;134(11-12):425-33. PMID: 35362792
- 5. Yang X, He H, Ye W, et al. Effects of Pulsed Electromagnetic Field Therapy on Pain, Stiffness, Physical Function, and Quality of Life in Patients With Osteoarthritis: A

- Systematic Review and Meta-Analysis of Randomized Placebo-Controlled Trials. *Phys Ther.* 2020;100(7):1118-31. PMID: 32251502
- 6. Chen L, Duan X, Xing F, et al. Effects of pulsed electromagnetic field therapy on pain, stiffness and physical function in patients with knee osteoarthritis: A systematic review and meta-analysis of randomized controlled trials. *Journal of rehabilitation medicine*. 2019;51(11):821-27. PMID: 31583420
- 7. Newberry SJ, FitzGerald J, SooHoo NF, et al. *Treatment of Osteoarthritis of the Knee: An Update Review.* Rockville MD, 2017, pp.
- 8. Negm A, Lorbergs A, Macintyre NJ. Efficacy of low frequency pulsed subsensory threshold electrical stimulation vs placebo on pain and physical function in people with knee osteoarthritis: systematic review with meta-analysis. Osteoarthritis and cartilage / OARS, Osteoarthritis Research Society. 2013;21(9):1281-9. PMID: 23973142
- 9. Yabroudi MA, Aldardour A, Nawasreh ZH, et al. Effects of the combination of pulsed electromagnetic field with progressive resistance exercise on knee osteoarthritis: A randomized controlled trial. *J Back Musculoskelet Rehabil*. 2024;37(1):55-65. PMID: 37718773
- 10. de Paula Gomes CAF, Politti F, de Souza Bacelar Pereira C, et al. Exercise program combined with electrophysical modalities in subjects with knee osteoarthritis: a randomised, placebo-controlled clinical trial. *BMC Musculoskelet Disord*. 2020;21(1):258. PMID: 32312265
- Khooshideh M, Latifi Rostami SS, Sheikh M, et al. Pulsed Electromagnetic Fields for Postsurgical Pain Management in Women Undergoing Cesarean Section: A Randomized, Double-Blind, Placebo-controlled Trial. *Clin J Pain.* 2017;33:142-47. PMID: 28060214
- 12. Bagnato GL, Miceli G, Marino N, et al. Pulsed electromagnetic fields in knee osteoarthritis: a double blind, placebo-controlled, randomized clinical trial. *Rheumatology (Oxford)*. 2016;55:755-62. PMID: 26705327
- 13. Nelson FR, Zvirbulis R, Pilla AA. Non-invasive electromagnetic field therapy produces rapid and substantial pain reduction in early knee osteoarthritis: a randomized double-blind pilot study. *Rheumatology international*. 2013;33(8):2169-73. PMID: 22451021
- 14. Ozguclu E, Cetin A, Cetin M, et al. Additional effect of pulsed electromagnetic field therapy on knee osteoarthritis treatment: a randomized, placebo-controlled study. *Clinical rheumatology*. 2010;29(8):927-31. PMID: 20473540
- 15. Guidance for industry: chronic cutaneous ulcer and burn wounds-developing products for treatment. *Wound Repair Regen.* 2001;9(4):258-68. PMID: 11679134
- 16. Zheng Y, Du X, Yin L, et al. Effect of electrical stimulation on patients with diabetes-related ulcers: a systematic review and meta-analysis. *BMC Endocr Disord*. 2022;22(1):112. PMID: 35477391
- 17. Aziz Z, Bell-Syer SE. Electromagnetic therapy for treating pressure ulcers. *The Cochrane database of systematic reviews.* 2015(9):CD002930. PMID: 26334539
- 18. Aziz Z, Cullum N. Electromagnetic therapy for treating venous leg ulcers. *The Cochrane database of systematic reviews.* 2015(7):CD002933. PMID: 26134172
- 19. Agency for Healthcare Research and Quality (AHRQ): Pressure Ulcer Treatment Strategies: Comparative Effectiveness. March 2021 [cited 10/30/2024]. 'Available from:' https://effectivehealthcare.ahrq.gov/products/pressure-ulcer-treatment.
- 20. Tassone EE, Page JC, Slepian MJ. Assessing the Effects of Pulsed Electromagnetic Therapy on Painful Diabetic Distal Symmetric Peripheral Neuropathy: A Double-Blind Randomized Controlled Trial. *J Diabetes Sci Technol.* 2023:19322968231190413. PMID: 37542366

- 21. Reinboldt-Jockenhöfer F, Traber J, Liesch G, et al. Concurrent optical and magnetic stimulation therapy in patients with lower extremity hard-to-heal wounds. *J Wound Care*. 2022;31(Sup6):S12-s21. PMID: 35678774
- 22. de Pedro Negri AM, Ruiz Prieto MJ, Díaz-Mohedo E, et al. Efficacy of Magnetic Therapy in Pain Reduction in Patients with Chronic Pelvic Pain: A Systematic Review. *Int J Environ Res Public Health.* 2022;19(10). PMID: 35627359
- 23. Vinolo-Gil MJ, Rodríguez-Huguet M, García-Muñoz C, et al. Effects of Peripheral Electromagnetic Fields on Spasticity: A Systematic Review. *J Clin Med.* 2022;11(13). PMID: 35807019
- 24. Kroeling P, Gross A, Graham N, et al. Electrotherapy for neck pain. *The Cochrane database of systematic reviews.* 2013(8):CD004251. PMID: 23979926
- 25. Hattapoglu E, Batmaz I, Dilek B, et al. Efficiency of pulsed electromagnetic fields on pain, disability, anxiety, depression, and quality of life in patients with cervical disc herniation: a randomized controlled study. *Turkish journal of medical sciences*. 2019;49(4):1095-101. PMID: 31385489
- 26. Kim CH, Wheatley-Guy CM, Stewart GM, et al. The impact of pulsed electromagnetic field therapy on blood pressure and circulating nitric oxide levels: a double blind, randomized study in subjects with metabolic syndrome. *Blood pressure*. 2020;29(1):47-54. PMID: 31394939
- 27. Ozdemir M, Yasar MF, Yaksi E. Effect of pulsed electromagnetic field therapy in patients with supraspinatus tendon tear. *Rev Assoc Med Bras (1992).* 2021;67(2):282-86. PMID: 34406254
- 28. Elshiwi AM, Hamada HA, Mosaad D, et al. Effect of pulsed electromagnetic field on nonspecific low back pain patients: a randomized controlled trial. *Brazilian journal of physical therapy*. 2019;23(3):244-49. PMID: 30177406
- 29. Multanen J, Hakkinen A, Heikkinen P, et al. Pulsed electromagnetic field therapy in the treatment of pain and other symptoms in fibromyalgia: A randomized controlled study. *Bioelectromagnetics*. 2018;39(5):405-13. PMID: 29709070
- 30. Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. *Arthritis care & research*. 2020;72(2):149-62. PMID: 31908149
- 31. Bannuru RR, Osani MC, Vaysbrot EE, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. *Osteoarthritis and cartilage / OARS, Osteoarthritis Research Society.* 2019;27(11):1578-89. PMID: 31278997
- 32. American Academy of Orthopaedic Surgeons. Management of Osteoarthritis of the Knee (Non-Arthroplasty). 2021. [cited 10/30/2024]. 'Available from:' https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/oak3cpg.pdf.
- 33. American Academy of Orthopaedic Surgeons. Management of Osteoarthritis of the Hip. 2023. [cited 10/30/2024]. 'Available from:' https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-hip/oah-cpg.pdf.
- 34. Association for the Advancement of Wound Care (AAWC) International Consolidated Venous Ulcer Guideline (ICVUG) 2015. [cited 10/30/2024]. 'Available from:' https://aawconline.memberclicks.net/assets/appendix%20c%20guideline%20icvug-textformatrecommendations-final%20v42%20changessaved18aug17.pdf.
- 35. Association for the Advancement of Wound Care (AAWC) Guideline of Pressure Ulcer Guidelines. [cited 10/30/2024]. 'Available from:' https://s3.amazonaws.com/aawc-new/memberclicks/AAWCPressureUlcerGuidelineofGuidelinesAug11.pdf.

36. Gould L, Stuntz M, Giovannelli M, et al. Wound Healing Society 2015 update on guidelines for pressure ulcers. *Wound Repair Regen.* 2016;24(1):145-62. PMID: 26683529

| | | CODES |
|-------|--------|--|
| Codes | Number | Description |
| CPT | 0766T | Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve |
| | 0767T | Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure) |
| | 0906T | Concurrent optical and magnetic stimulation (COMS) therapy, wound assessment and dressing care; first application, total wound(s) surface area less than or equal to 50 sq cm. For purposes of reporting 0906T, 0907T for concurrent optical and magnetic stimulation (COMS) therapy, the treatment area is limited to 50 sq cm of |
| | 0907T | skin-surface area per application. Concurrent optical and magnetic stimulation (COMS) therapy, wound assessment and dressing care; each additional application, total wound(s) surface area less than or equal to 50 sq cm (List separately in addition to code for primary procedure) |
| HCPCS | E0761 | Non-thermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device. |
| | E0769 | Electrical stimulation or electromagnetic wound treatment device, not otherwise classified |
| | G0295 | Electromagnetic stimulation, 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 |

Date of Origin: October 2020