

Electrical Stimulation and Electromagnetic Therapy for the Treatment of Arthritis

Effective: May 1, 2017

Next Review: June 2018

Last Review: April 2017

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

Electrical stimulation and electromagnetic therapy have been used as a non-surgical treatment of osteoarthritis and rheumatoid arthritis.

MEDICAL POLICY CRITERIA

Electrical stimulation and electromagnetic therapy for the treatment of osteoarthritis and rheumatoid arthritis is considered **investigational**.

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

CROSS REFERENCES

1. [Electrical Stimulation Devices Index](#), DME, Policy No. 83
2. [Interferential Current Stimulation](#), DME, Policy No. 83.07
3. [Electrostimulation and Electromagnetic Therapy for the Treatment of Wounds](#), DME, Policy No. 83.09
4. [Transcutaneous Electrical Modulation Pain Reprocessing](#), Medicine, Policy No. 143
5. [Percutaneous Neuromodulation Therapy \(PNT\)](#), Surgery, Policy No. 44

BACKGROUND

Electrical and electromagnetic stimulation have been proposed for use in improving functional status and relieving pain related to osteoarthritis and rheumatoid arthritis unresponsive to other standard therapies. Noninvasive electrical stimulators generate a weak electrical current within the target site using capacitive coupling, pulsed electromagnetic fields, or combined magnetic fields. In capacitive coupling, small skin pads/electrodes are placed on either side of the knee or wrist. For pulsed electromagnetic fields, treatment is delivered via treatment coils which are placed over the skin. While combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying magnetic field onto an additional static magnetic field. These electrical stimulation methods are provided by an electronic device that noninvasively delivers sub-sensory low-voltage, monophasic electrical field to the target site of pain.

REGULATORY STATUS

Devices with U.S. Food and Drug Administration (FDA) 510(k) clearance for adjunctive treatment of knee pain in osteoarthritis, include:

- RS-4i® Sequential Stimulator (RS Medical); FDA Product Codes: IPF, LIH
- OrthoCor™ Active Knee System (OrthoCor Medical); FDA Product Codes: ILX, IMD

Devices which have received 510(k) clearance for the treatment of rheumatoid arthritis of the hand, in addition to osteoarthritis of the knee, include:

- MedRelief® ST Series™: ST-150, ST-200 and ST-300 (Healthonics, Inc.); FDA Product Codes: GZJ, NYN
- BioniCare BIO-1000™ (BioniCare Medical Technologies, Inc.); FDA Product Code: NYN

Devices which have received 510(k) clearance for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue include:

- The SofPulse™ (also Torino II, 912-M10, and Roma3™, Ivivi Health Sciences); FDA Product Codes ILX
- In 2017, the ActiPatch® (BioElectronics) was cleared for marketing by the FDA through the 510(k) process for over-the-counter use for adjunctive treatment of plantar fasciitis of the heel and osteoarthritis of the knee. Product code: PQY.

Note: Treatment of osteoarthritis or rheumatoid arthritis with other types of electrical stimulation is considered separately (see Cross Reference section above).

EVIDENCE SUMMARY

Interpretation of evidence regarding treatments for arthritis can be confounded by many factors including the natural variation of disease remission and progression in individual patients and subjective reporting. 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 electrical stimulation or electromagnetic therapy 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 electrical stimulation device should be compared with other forms of conservative treatment for arthritis. 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

In 2015, Zeng et al. published results from a systematic review (SR) with a network meta-analysis that investigated different electrical stimulations (ES) therapies for pain relief of patients with knee osteoarthritis.^[1] Twenty-seven trials and six kinds of ES therapies were included in the review. The ES therapies included: high-frequency transcutaneous electrical nerve stimulation (h-TENS), low-frequency transcutaneous nerve stimulation (i-Tens), neuromuscular electrical stimulation (NMES), interferential current (IFC), pulsed electrical stimulation (PES), and noninvasive interactive neurostimulation (NINO) were all included. The authors concluded that these studies had a number of methodological limitations, including but not limited to, low-quality evidence, heterogeneity, and small sample sizes, all of which were a threat to the validity of the studies; therefore, they were unable to determine the efficacy of electrical stimulation as a therapy for pain relief in patients with knee osteoarthritis.

In 2013 Li et al. published a SR of transcutaneous electrical stimulation for osteoarthritis of the knee, included nine studies, with a total of 636 patients.^[2] Meta-analysis found that participants who were randomized to pulsed electrical stimulation (PES) or pulsed electromagnetic field (PEMF) rated their pain relief as greater than sham-treated patients by 15.10 more on a scale of 0 to 100 but found no statistically significant effect on function or quality of life. There was a high risk of bias for incomplete outcome data in 3 studies. For all nine studies, there were inadequacies in reporting of study design and conduct, making it unclear whether there was bias due to selective outcome reporting.

Also in 2013 by Negm et al, 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 (OA).^[3] 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.

PULSED ELECTRICAL STIMULATION

Randomized Controlled Trials

In 2011, Fary et al. reported results from a randomized double-blind sham-controlled trial of pulsed electrical stimulation in 70 patients with osteoarthritis of the knee.^[4] The device used in this study was a commercially available transcutaneous electrical nerve stimulator (TENS) unit that was modified to provide pulsed electrical stimulation. Participants were instructed to apply the device for a minimum of six hours a day. In the placebo group, the device turned itself off after three minutes. After 26 weeks of treatment, 59% of patients using the active device and

36% of controls had achieved target usage based on patient-maintained logs. Intention-to-treat analysis showed a statistically significant improvement in visual analog score (VAS) for pain over 26 weeks in both groups, but no difference between groups (VAS of 20 vs. 19 for controls on a 100-mm scale). There was no significant difference between groups in the proportion of patients who achieved a clinically relevant 20-mm improvement in VAS pain score at 26 weeks (56% vs. 44% of controls). There were no significant differences between groups for changes in WOMAC pain, function, and stiffness scores, short-form 36 (SF-36) physical and mental component summary scores, patient's global assessment of disease activity, or activity measures. Results from this study do not indicate that treatment with electrical stimulation is superior to placebo.

In 2007, Garland et al. published results from an industry-sponsored, randomized, double-blind sham-controlled study of the BioniCare pulsed electrical stimulation device was reported for 58 patients with osteoarthritis of the knee.^[5] Due to protocol violations from one of the centers (i.e., other new treatments were provided during the study) 42 of the original 100 subjects were excluded from the analysis. Patients were instructed to wear the devices for 6 hours or more each day, typically at night. Compliance was monitored with a timer in the device and found to be similar in the two groups (63% to 66%, respectively). At the end of three months of use the percentage of patients who improved 50% or more was significantly greater in the active group than in the sham group for patient global (39% vs. 5%, respectively), patient pain (44% vs. 16%, respectively) and WOMAC pain (39% vs. 11%, respectively) subscales. The percentage of patients who improved 50% or more on the WOMAC stiffness (28% vs. 5%, respectively) and WOMAC function (23% vs. 5%, respectively) subscales showed the same trend but did not reach statistical significance in this sample.

PULSED SHORT-WAVE ELECTROMAGNETIC FIELD STIMULATION

Randomized Controlled Trials

Bagnato (2016) reported a double-blind, sham-controlled trial of nightly treatment (12 hours) with a wearable ActiPatch®, an electromagnetic device.^[6] Sixty-six patients with OA 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 et al. published results from a well-conducted, randomized, double-blind, placebo-controlled pilot study regarding PEMF therapy in 34 patients with osteoarthritis.^[7] 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 2011, Fukada et al. published results from a double-blinded RCT from South America that included 121 women who were divided into four groups, low (19 min treatment) or high-dose (38 min treatment) short-wave electrical field stimulation (9 sessions over 3 weeks), placebo, or no-treatment control.^[8] Pain and function were measured with a numeric rating scale (NRS) and the Knee Osteoarthritis Outcome Score (KOOS) at baseline, immediately after treatment, and at one-year follow-up. Except for the untreated controls, both patients and the physical therapist evaluator were blinded throughout the one year follow-up. When measured immediately after treatment, both the low and high-dose groups showed significantly greater improvement than the control groups in the numeric rating scale and KOOS subscales. For example, the NRS decreased from 7.7 to 6.9 in the placebo group, from 7.1 to 3.8 in the low-dose group, and from 6.7 to 4.6 in the high dose group. The percentage of patients who attained the minimal clinically important difference of two points on the NRS was 15% in the control group, 15% in the placebo group, 75% in the low-dose group, and 50% in the high-dose group. At the one year follow-up the low-dose group, but not the high-dose group, sustained significant improvement on three of the five KOOS subscales. Since there was a 36% dropout rate (from patients lost to follow-up, patients who received other therapies, and patients who had a total knee replacement), analyses were performed both per-protocol and by last observation carried forward; these analyses yielded similar results.

In 2010 Ozguclu et al. published results from a double-blind randomized controlled trial investigated the effect of pulsed electromagnetic field therapy (PEMF) in 40 patients with knee osteoarthritis.^[9] 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.

PEMF PLUS PHYSICAL THERAPY VS SHAM PEMF PLUS PHYSICAL THERAPY

A 2016, double-blind, sham-controlled randomized trial of 40 patients with knee OA evaluated 1 hour of physical therapy plus PEMF.^[10] Both groups, physical therapy plus 20 minutes of PEMF (PMT Quattro PRO; ASA) and physical therapy plus 20 minutes of sham PEMF showed equally significant improvements in pain scores.

PRACTICE GUIDELINE SUMMARY

AMERICAN COLLEGE OF RHEUMATOLOGY

In 2015, ACR published recommendations for the treatment of rheumatoid arthritis.^[11] All recommended treatments were pharmacologic. Use of electrical stimulation for the treatment of rheumatoid arthritis was not addressed.

In 2012, the American College of Rheumatology (ACR) published recommendations on the use of nonpharmacologic and pharmacologic therapies for OA.^[12] The recommendations were classified as either “strong,” “conditional,” or “none.” ACR issued a conditional recommendation for the use of transcutaneous electrical stimulation for the treatment of OA of the knee. This recommendation should only be considered for patients with chronic moderate

or severe pain who are candidates for total knee arthroplasty, but who are unwilling or unable to undergo the procedure due to comorbidities or concomitant use of medications that are contraindications to surgery or are advised against the procedure by a surgeon. ACR is accepting letters of interest to participate in updating these guidelines. Expected publication of updated guidelines is 2019.

OSTEOARTHRITIS RESEARCH SOCIETY INTERNATIONAL

In 2014, the Osteoarthritis Research Society International (OARSI) published evidence-based consensus guidelines for nonsurgical management of knee osteoarthritis (OA).^[13] Twenty-nine treatment modalities were evaluated for four patient groups: knee only OA, knee-only OA with comorbidities, multijoint OA, and multijoint OA with comorbidities. Neuromuscular electrical stimulation was considered “not appropriate” for all four groups. Evidence consisted of a SR with meta-analysis of randomized controlled trials. The quality of the evidence was considered fair.

THE AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

In 2013, the American Academy of Orthopaedic Surgeons (AAOS) published guidelines on the treatment of osteoarthritis of the knee.^[14] Due to the overall inconsistent finding for electrotherapeutic modalities, they were unable to make a recommendation for or against their use in patients with symptomatic osteoarthritis of the knee.

SUMMARY

There is not enough research to show that electrical stimulation or electromagnetic therapy improves health outcomes for people with osteoarthritis or rheumatoid arthritis. No clinical guidelines based on research recommend electrical stimulation or electromagnetic therapy for osteoarthritis or rheumatoid arthritis. Therefore, use of electrical stimulation or electromagnetic therapy as treatment for osteoarthritis and/or rheumatoid arthritis is considered investigational.

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CODES

Codes	Number	Description
CPT	None	
HCPCS	E0762	Transcutaneous electrical joint stimulation device system

Date of Origin: January 2005