Electrical Stimulation for the Treatment of Arthritis

Effective: August 1, 2024

Next Review: June 2025
Last Review: June 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

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

MEDICAL POLICY CRITERIA

Notes:

- Electrical stimulation as a treatment of pain and other musculoskeletal conditions is considered in separate plan Medical Policies.
- Electromagnetic therapy as a treatment of arthritis is considered in a separate plan Medical Policy. See Cross References.

Electrical stimulation 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. Interferential Current Stimulation, DME, Policy No. 83.07

2. Electrical Stimulation for the Treatment of Wounds, DME, Policy No. 83.09
3. Electromagnetic Therapy, DME, Policy No. 83.13
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. 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

Transcutaneous electrical nerve stimulator devices which have received 510(k) clearance for the treatment of pain associated with rheumatoid arthritis of the hand, in addition to pain associated with osteoarthritis of the knee, include:

- MedRelief® ST Series™: ST-150, ST-200 and ST-300 (Healthonics, Inc.); FDA Product Codes: GZJ, NYN, K060669
- BioniCare BIO-1000™ (BioniCare Medical Technologies, Inc.); FDA Product Code: NYN

An example of a transcutaneous electrical nerve stimulator device which has received 510(k) clearance for relief of chronic intractable pain or as an adjunctive treatment of post-surgical or post-traumatic acute pain is:

- MedRelief® ST Series™ SE-100; FDA product codes GZJ, NYN, K060669

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 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.

ELECTRICAL STIMULATION

Systematic Reviews

Wu (2022) published a systematic review (SR) with meta-analysis of studies using transcutaneous electrical stimulation (TENS) in the treatment of knee osteoarthritis.[1] A total of 29 trials were included in the review (n=1603), and data from 919 patients were included in the meta-analysis. Sample sizes of included studies ranged from 16 to 150 patients. Risk of bias was assessed by the Cochrane Risk of Bias Tool; 16 trials (55%) had high risk of bias and (46%) had low risk of bias. For visual analogue scale (VAS) pain ratings, low certainty of evidence was found that active TENS provided significant pain relief compared to placebo (SMD -3.78, 95% CI -9.70 to 2.14) and that TENS or TENS combined with other interventions was superior to other interventions such as exercise, education, and ultrasound immediately following the intervention (SMD -6.25, 95% CI -12.81 to 0.30) and in the medium term (SMD -5.85, 95% CI -9.43 to -2.37). Very-low certainty of evidence was found that TENS or TENS combined with other interventions is inferior to other interventions for pain in the long term (greater than four weeks, SMD -5.83, 95% CI -7.62 to -4.03). Low certainty of evidence was found that TENS combined with other interventions is superior to other interventions for knee function in the medium and long term (SMD -4.20, 95% CI -13.15 to 4.75 and SMD -0.69, 95% CI -4.10 to 2.73, respectively). Noted limitations to the available data include heterogeneity in study design (control used, electrode placement stimulation parameters, timing of stimulation) as well as high risk of bias.

A 2018 SR by Briani reported evidence from RCTs on the effectiveness of conservative interventions on quality of life and psychosocial factors in individuals with knee osteoarthritis.[2] The SR concluded that there was limited evidence that a combined treatment of yoga, transcutaneous electrical stimulation (TENS) and ultrasound may be effective in improving quality of life.

In 2015, Zeng published results from a SR with a network meta-analysis that investigated different electrical stimulations (ES) therapies for pain relief of patients with knee osteoarthritis.[3] 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 (NIN) 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 published a SR of transcutaneous electrical stimulation for osteoarthritis of the knee, included nine studies, with a total of 636 patients.[4] 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 three 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, 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 (OA).[5] 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

Systematic Review

Tong (2022) published a SR of 11 RCTs in which patients with osteoarthritis received pulsed electromagnetic fields or control treatment.[6] Six studies had a sham group and five studies used other treatments including hot packs, TENS, physiotherapy, and ultrasound (US). 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 McMaster Universities Osteoarthritis Index (WOMAC) scores. Compared to controls, pulsed electromagnetic field stimulation significantly reduced pain (SMD, 0.71; 95% CI, 0.08 to 1.34; p=0.03; I2=93%). There were also significant differences in stiffness (SMD, 1.34; 95% CI, 0.45 to 2.23; p=0.003; I^2=99%) and physical function (SMD, 1.52; 95% CI, 0.49 to 2.55; p=0.004; I^2=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. Risk of bias was high in six studies, moderate in two studies, and low in three studies.

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.[7] 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 five-times chair stand test and walking speed test faster at post-treatment timepoints compared to baseline; however none of the discussed study outcomes were significantly different between the pulsed electromagnetic field therapy plus PRE or PRE alone groups.

Reichenbach (2022) published the results of a multi-site randomized controlled trial (RCT) evaluating the safety and effectiveness of TENS at relieving pain and improving physical function in patients with knee osteoarthritis.[8] Patients were randomized to three weeks of

treatment with TENS (n=108) or placebo TENS (n=112) and the pre-specified primary endpoint was knee pain at the end of treatment assessed with the Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain subscale . Secondary outcomes were physical function and safety. No statistically significant difference between TENS and placebo TENS groups was found in pain or any secondary measures during the trial or at the end of treatment (mean difference -0.06; 95%CI -0.41 to 0.29; p=0.74). The occurrence of adverse events was similar across groups, with 10.4% and 10.6% of patients reporting events in the TENS and placebo TENS groups, respectively (p=0.95).

de Paula Gomes (2020) conducted a prospective RCT evaluating the effects of an exercise program alone or combined with electrophysical treatment modalities in patients with knee osteoarthritis (n=100).[9] 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 a duration of eight weeks. A significant improvement in 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.

In 2011, Fary reported results from a randomized double-blind sham-controlled trial of pulsed electrical stimulation in 70 patients with osteoarthritis of the knee.[10] The device used in this study was a commercially available transcutaneous electrical nerve 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 published results form 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.[11] 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 six 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.

In 2011, Fukada published results from a double-blinded RCT from South America that included 121 women who were divided into four groups, low (19 minute treatment) or high-dose (38 minute treatment) short-wave electrical field stimulation (nine sessions over three weeks), placebo, or no-treatment control.[12] The treatment was delivered by the Diatermed II device. 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.

PRACTICE GUIDELINE SUMMARY

AMERICAN COLLEGE OF RHEUMATOLOGY

In 2019, the American College of Rheumatology (ACR) released guidelines for the management of osteoarthritis (OA) of the hand, hip, and knee.[13] The guidelines do not mention pulsed electrical stimulation and recommend against transcutaneous electrical stimulation for patients with knee and/or hip OA.

The 2021, the ACR an updated guideline for the treatment of rheumatoid arthritis.[14] All recommended treatments were pharmacologic. Use of electrical stimulation for the treatment of rheumatoid arthritis was not addressed.

In 2012, the ACR published recommendations on the use of nonpharmacologic and pharmacologic therapies for OA.[15] 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.

OSTEOARTHRITIS RESEARCH SOCIETY INTERNATIONAL

In 2019, the Osteoarthritis Research Society International (OARSI) published updated evidence-based consensus guidelines for nonsurgical management of knee osteoarthritis (OA).[16] Sixty treatment modalities were evaluated for three patient groups: knee only OA, hip, and multijoint osteoarthritis. Neuromuscular electrical stimulation was considered “strongly recommended against” for all groups. due to low quality evidence from trials with small sample sizes and insufficient duration of follow-up.

THE AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS

In 2021, the American Academy of Orthopaedic Surgeons (AAOS) published updated guidelines on the treatment of osteoarthritis of the knee.[17] Due to inconsistent evidence and/or feasibility issues, the strength of recommendation for electrotherapeutic modalities was downgraded to "limited". A “limited” recommendation is defined as: evidence from one or more “Low” quality studies with consistent findings or evidence from a single “Moderate” quality study recommending for or against the intervention.

In 2017, the American Academy of Orthopaedic Surgeons (AAOS) published guidelines on the treatment of osteoarthritis of the hip.[18] Use of electrical stimulation for the treatment of osteoarthritis of the hip was not addressed.

SUMMARY

There is not enough research to show that electrical stimulation improves health outcomes for people with osteoarthritis or rheumatoid arthritis. No clinical guidelines based on research recommend electrical stimulation for osteoarthritis or rheumatoid arthritis. Therefore, use of electrical stimulation 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*