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Medical Policy Manual

Topic: Electrical Stimulation and Electromagnetic Therapy for the Treatment of Arthritis

Date of Origin: January 4, 2005

Section: DME

Last Reviewed Date: June 2014

Policy No: 83.10

Effective Date: September 1, 2014

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 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)
- OrthoCor™ Active Knee System (OrthoCor Medical)

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.)
- BioniCare BIO-1000™ (BioniCare Medical Technologies, Inc.)

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)

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

MEDICAL POLICY CRITERIA

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

SCIENTIFIC EVIDENCE

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. 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.

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, evidence from large, rigorously designed randomized, placebo-controlled trials, ideally observed over an extended period of time, is needed to adequately assess electrical stimulation outcomes.

Literature Appraisal

The available published literature investigating electrical stimulation and electromagnetic therapy as a treatment of arthritis is limited to a Cochrane review, several small randomized controlled trials (RCTs), including sham-controlled RCTs which form the focus of this review, as well as several non-randomized studies.

<u>Pulsed Electrical Stimulation</u>

Cochrane Review

- An update to a Cochrane review of transcutaneous electrical stimulation for osteoarthritis of the knee first published in 2009 was released in 2010.[1] The authors concluded:

  "In this update, we could not confirm that transcutaneous electrostimulation is effective for pain relief. The current systematic review is inconclusive, hampered by the inclusion of only small trials of questionable quality. Appropriately designed trials of adequate power are warranted."

They did not include a separate conclusion on the use of pulsed electrical stimulation; however, two RCTs specific to this type of electrical stimulation were included in the review.[2,3]

Randomized Controlled Trials (RCTs)

- 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 TENS (transcutaneous electrical nerve stimulator) unit that was modified to provide pulsed electrical stimulation. Participants were instructed to apply the device for a minimum of 6 hours a day. In the placebo group, the device turned itself off after 3 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.

- Zizic and colleagues reported on a multicenter, double-blind, randomized, placebo-controlled trial of pulsed electrical stimulation to assess pain relief and functional improvements in 78 patients with osteoarthritis of the knee.[2] Patients used the BioniCare or placebo device for 6 to 10 hours daily for 4 weeks and were allowed to continue nonsteroidal anti-inflammatory drug therapy. The placebo group used a sham device that produced a sensation similar to the BioniCare device. Both patient groups were instructed to reduce the stimulation level to just below the sensation threshold. In the placebo group, the device would then turn itself off.

  The primary outcomes assessed at baseline and after 4 weeks of treatment included patient assessment of pain and function, and physician global evaluation of the patients' condition. The authors reported that the BioniCare group had statistically significant improvement, defined as improvement of at least 50%, in each of the primary outcomes assessed. The authors also assessed 6 secondary outcomes including duration of morning stiffness, range of motion, knee tenderness, joint swelling, joint circumference, and walking time. However, only a decrease in mean morning stiffness in the BioniCare group was statistically significant. While this study reported short-term improvements with pulsed electrical stimulation using the BioniCare device, the authors noted that larger, long-term studies were warranted.

  This trial was included in a Cochrane review by Hulme et al., regarding electromagnetic fields for the treatment of osteoarthritis which concluded there may be some benefit, but further studies are

needed.[5] The Cochrane review also noted that the trial was rated of high quality, but it did not describe the randomization process; it was funded by the manufacturer; and it did not focus on outcomes of clinical significance.

- 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.[3] 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 2 groups (63% to 66%, respectively). At the end of 3 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.

At least 1 randomized controlled trial which did not include a placebo comparison group was been identified as well.[6] However, comparison with placebo is needed in order to isolate any treatment effects to the electrical stimulation device. The lack of a placebo comparison renders interpretation of findings unclear.

Nonrandomized Studies

One non-randomized observational study[7] reported on the use of pulsed electrical stimulation for knee osteoarthritis. However, results from this study is limited by lack of randomization to comparative treatment groups (including a sham treatment group), without which it not possible to isolate the independent treatment effect of electrical stimulation from natural disease progression or standard medical care.

Pulsed Short-wave Electromagnetic Field Stimulation

Cochrane Review

Li and colleagues published an updated review of the 2002 Hulme Cochrane review[5] which included 9 RCTs, regarding the efficacy of electromagnetic therapy for the treatment of osteoarthritis as compared to placebo or sham. Studies were required to have at least 4 weeks treatment duration to be included in the review and six new studies were added to the previous review of 3 trials considered by Hulme. Authors reported significant improvement in pain relief of 15.10 points more on a scale of 0 to 100 (MD 15.10, 95% CI 9.08 to 21.13; absolute improvement 15%) after 4 to 26 weeks' treatment with electromagnetic field treatment compared to placebo. However, no statistically significant effect was observed in physical function or quality of life. No data were available regarding radiographic changes. Overall, the authors' conclusions remained unchanged from the previous assessment. Authors indicated that additional studies are needed to confirm whether electromagnetic therapy adds clinically significant improvement in physical function or quality of life outcomes.

Randomized Controlled Trials (RCTs)

- In 2011, Fukada et al. reported a double-blinded RCT from South America that included 121 women who were divided into 4 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 1-year follow-up. Except for the untreated controls, both patients and the physical therapist evaluator were blinded throughout the 1-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 2 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 1-year follow-up the low-dose group, but not the high-dose group, sustained significant improvement on 3 of 5 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.

- A 2010 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 5 times per week for 2 weeks, along with isometric knee exercises performed at home. After 2 weeks, both groups showed improvement in pain and functional scores; there were no significant differences between the 2 groups.

- In 2013, Nelson et al. reported a well-conducted, randomized, double-blind, placebo-controlled pilot study regarding PEMF therapy in 34 patients with osteoarthritis.[10] In addition to having knee pain with confirmed articular cartilage loss and an initial VAS score of 4 or more, only patients who had at least 2 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 1 and 2, and then for weeks 5 and 6. By the end of the study, 3 active and 7 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.

Clinical Practice Guidelines

The American College of Occupational and Environmental Medicine (ACOEM)[11]

In 2011, the ACOEM updated their guidelines regarding treatment for knee disorders and indicated that there was insufficient evidence to recommend electric stimulation therapies for knee pain or knee osteoarthrosis.

In 2008, the ACOEM published guidelines regarding treatment for chronic pain and indicated that there is no evidence to support the use of electrical therapies as a method for managing chronic pain.[12]

Summary

Based on the lack of long-term objective outcomes from well-designed clinical trials, conclusions cannot be reached concerning the effectiveness of electrical stimulation or electromagnetic therapy in the treatment of rheumatoid arthritis and osteoarthritis. Evidence remains insufficient to evaluate the effect of this treatment on health outcomes. In addition, no evidence-based clinical practice guidelines were identified which support the use of electrical stimulation or electromagnetic therapy as a treatment for arthritis. Therefore, use of electrical stimulation or electromagnetic therapy as treatment for rheumatoid arthritis and/or osteoarthritis is considered investigational.

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Transcutaneous Electrical Modulation Pain Reprocessing, Medicine, Policy No. 143

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CODES	NUMBER	DESCRIPTION
CPT	None	
HCPCS	E0762	Transcutaneous electrical joint stimulation device system