
Medical Policy



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BCN Policy Effective Date: 7/13/23
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Title: Electrical Stimulation for the Treatment of Arthritis

Description/Background

Electrical and electromagnetic stimulation are being investigated to improve functional status and relieve pain related to osteoarthritis (OA) and rheumatoid arthritis (RA) unresponsive to other standard therapies. Noninvasive electrical stimulators generate a weak electrical current within the target site using pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads or electrodes are placed on either side of the knee or wrist. Electrical stimulation is provided by an electronic device that noninvasively delivers a subsensory low-voltage, monophasic electrical field to the target site of pain. Pulsed electromagnetic fields are delivered via treatment coils that are placed over the skin. Combined magnetic fields deliver a time-varying field by superimposing that field onto an additional static magnetic field.

In basic research studies, pulsed electrical stimulation has been shown to alter chondrocyte-related gene expression in vitro and to have regenerative effects in animal models of cartilage injury. Therefore, pulsed electrical stimulation is proposed to be similar to bone stimulator therapy for fracture nonunion.

Regulatory Status:

The BionCare Bio-1000™ stimulator (VQ OrthoCare) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process in 1997 to deliver pulsed electrical stimulation for adjunctive treatment of osteoarthritis of the knee, then later for rheumatoid arthritis of the hand. The FDA originally determined that this device was substantially equivalent to transcutaneous electrical nerve stimulation (TENS) devices. The manufacturer requested reclassification due to the fact that the target tissue is joint tissue, not nerve. In 2006, the FDA reclassified the device as a transcutaneous electrical stimulator for

arthritis.¹ The BionCare System consists of an electronic stimulator device with electrical leads placed over the affected area and held in place with a lightweight, flexible wrap, and self-adhesive fasteners. The battery-powered device delivers small pulsed electrical currents of 0.0-V to 12.0-V output. FDA product code: NYN.

The OrthoCor™ Active Knee System (OrthoCor Medical; acquired by Caerus Corp. in 2016) uses pulsed electromagnetic field energy at a radio frequency of 27.12 MHz to treat pain. In 2009, the OrthoCor Knee System was cleared for marketing by the FDA through the 510(k) process and is classified as a shortwave diathermy device for use other than applying therapeutic deep heat (K091996, K092044). It is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue and for the treatment of muscle and joint aches and pain associated with overexertion, strains, sprains, and arthritis. The system includes single-use packs (pods) that deliver hot or cold. The predicate devices are the OrthoCor (K091640) and Ivivi Torino II™ (K070541). FDA product code: ILX.

In 2008, the SofPulse™ (also Torino II, 912-M10, and Roma3™, Ivivi Health Sciences, renamed Amp Orthopedics) was cleared for marketing by the FDA through the 510k process as a short-wave diathermy devices that apply electromagnetic energy at a radiofrequency of 27.12 MHz (K070541). The device is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue. The Palermo device (Ivivi Health Sciences) is a portable battery-operated device. FDA product code: ILX.

In 2017, the ActiPatch® (BioElectronics) was cleared for marketing by FDA through the 510(k) process for nonprescription use for adjunctive treatment of plantar fasciitis of the heel and osteoarthritis of the knee (K152432). FDA product code: PQY. In January 2020, the ActiPatch indications for use were broadened to adjunctive treatment of musculoskeletal pain (K192234).

With the exception of ActiPatch, nonprescription devices are not evaluated in this review.

Medical Policy Statement

Electrical joint stimulation for the treatment of osteoarthritis and/or rheumatoid arthritis is experimental/investigational. It has not been scientifically demonstrated to improve patient clinical outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes (*Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.*)

Established codes:

N/A

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Clinical Context and Therapy Purpose

The purpose of pulsed electrical or electromagnetic stimulation is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as pharmacological therapy and physical therapy, in patients with arthritis.

The question addressed in this evidence review is: does the use of pulsed electrical or electromagnetic stimulation improve health outcomes in patients with pain related to osteoarthritis (OA) and rheumatoid arthritis?

The following **PICO** was used to select literature to inform this review.

Populations

The relevant population of interest are individuals with OA and rheumatoid arthritis.

Interventions

The therapy being considered is pulsed electrical or electromagnetic stimulation. The various forms of stimulation involved in this type of therapy include pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads or electrodes are placed on either side of the knee or wrist. Electrical stimulation is provided by an electronic device that noninvasively delivers a subsensory low-voltage, monophasic electrical field to the target site of pain. Pulsed electromagnetic fields are delivered via treatment coils placed over the skin. Combined magnetic fields deliver a time-varying field by superimposing that field onto an additional static magnetic field.

Comparators

Comparators of interest include pharmacological therapy and physical therapy. Treatment for arthritis includes physical exercise, self-care, NSAIDs, topical analgesics, and surgical interventions.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, health status measures, and treatment-related morbidity.

The existing literature evaluating pulsed electrical or electromagnetic stimulation as a treatment for arthritis has varying lengths of follow-up as long as one year. While studies described below all reported at least one outcome of interest, 6-12 months duration of follow-up is desirable to assess outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- d. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Electrical Versus Electromagnetic Stimulation

Systematic Reviews

Three recent systematic reviews reached somewhat different conclusions on the use of electric and electromagnetic field stimulation for treating knee osteoarthritis. Table 1 provides a comparison of trials included in these systematic reviews, Table 2 is a summary of relevant characteristics, and Table 3 summarizes key results.

Yang et al (2020) published a systematic review evaluating the effects of pulsed electromagnetic field therapy on pain, stiffness, physical function, and quality of life in patients with osteoarthritis.² The meta-analysis included 15 small, sham- or placebo-controlled studies published between 1993 and 2016 (N=985 patients). Only 2 studies were deemed to be at low risk of bias. Overall, the quality of evidence was deemed low or very low. A statistically significant beneficial treatment effect was noted for pain (standardized mean difference [SMD], 1.06; 95% confidence interval [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 pulsed electromagnetic field therapy, with study follow-up durations ranging from 10 days to 12 weeks. Additionally, the high levels of heterogeneity across the outcome measures made harmonization difficult, the included studies had small sample sizes, and there was a lack of an intention-to-treat analysis in many of the included studies.

A systematic review by Negm et al (2013), which included 7 small sham controlled randomized trials examined pulsed electrical stimulation (PES) or pulsed electromagnetic field (PEMF) for the treatment of knee osteoarthritis (OA).³ The trials were published between 1994 and 2011, 5 were conducted outside of the United States, and only the trial by Fary et al (2011)⁴ 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 selected studies was limited, including a high risk of bias, inconsistent results, and imprecise estimates of treatment effect (wide CIs around estimates) due to small sample sizes.

A 2013 Cochrane review on PES and PEMF included 9 studies, with a total of 636 patients that were published between 1993 and 2013.⁵ Meta-analysis found that participants who were randomized to PES or 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 due to incomplete outcome data in 3 studies. For all 9 studies, there were inadequacies in reporting of study designs and trial conduct, making it unclear whether there were selective outcomes reporting bias. The major limitation of the review was the small number of contributing studies that could be included, which also prevent a planned subgroup analysis of variations in treatment.

A number of the trials included in these systematic reviews are described briefly in the pulsed electrical stimulation and pulsed electromagnetic stimulation sections below.^{6,7,8,9,10,11,12,13}

Table 1. Comparison of Studies Included in Systematic Reviews/Meta-Analyses.

Study	Yang et al. (2020) ²	Negm et al (2013) ³	Li et al (2013) ⁵
Trock et al (1993) ¹⁴	X		X
Trock et al (1994) ¹⁵	X	X	X
Jacobson et al (2001) ¹⁶	X		
Pipitone et al (2001) ¹⁷	X	X	X
Thamsborg et al (2005) ¹⁸	X	X	X
Sutbeyaz et al (2006) ¹⁹	X		
Ay et al (2009) ²⁰	X	X	

Kulcu et al (2009) ^{21,}	X		
Ozguclu et al (2010) ^{13,}	X		X
Moldovan et al (2012) ^{22,}	X		
Pavlovic et al (2012) ^{23,}	X		
Kanat et al (2013) ^{24,}	X		
Nelson et al (2013) ^{10,}	X		X
Wuschech et al (2015) ^{9,}	X		
Bagnato et al (2016) ^{8,}	X		
Dundar et al (2016) ^{12,}	X		
Garland et al (2007) ^{6,}		X	
Fary et al (2011) ^{4,}		X	X
Nicolakis et al (2002) ^{25,}			X
Zizic et al (1995) ^{7,}			X

Table 2. Systematic Review/Meta-Analyses Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Yang et al. (2020) ²	Until April 2019	16	Adults (≥18 years of age) with osteoarthritis (self-reported or clinically diagnosed) receiving pulsed electromagnetic field therapy (or in combination with usual care) as the primary treatment intervention	1078 (27-176)	RCT	Treatment time: 10 days to 6 weeks
Negm et al (2013) ³	Until April 2012	7	Adults (>30 years of age) with clinically and/or radiologically confirmed knee osteoarthritis receiving pulsed electromagnetic field or pulsed electrical stimulation at low frequency (≤100 Hz)	459 (40-84)	RCT	Treatment time: 2 to 26 weeks
Li et al (2013) ⁵	Until October 2013	9	Adults (≥18 years of age) with clinical or radiological	636 (27-167)	RCT	Treatment time: 4 or more weeks

			confirmation (or both) of osteoarthritis receiving any type of pulsed electromagnetic field or pulsed electrical stimulation			
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RCT: randomized controlled trial.

Table 3. Systematic Review and Meta-Analyses Results

Study	Pain	Stiffness	Physical Function	Quality of Life	Adverse Event
Yang et al. (2020) ²					
Total N	N=985	N=404	N=457		
Pooled SMD (95% CI)	1.06 (0.61 to 1.51)	0.37 (0.07 to 0.67)	0.46 (0.14 to 0.78)		
I2 (p)	90% (<.00001)	53% (.05)	63% (.009)		
Negm et al (2013) ³					
Total N	N=459	NR	N=456	N=139	N=128 (skin rash)
Pooled SMD (95% CI)	0.08 (-0.17 to 0.32)		0.22 (0.04 to 0.41)	Highly heterogeneous result	RR 0.96 (0.45 to 2.03)
I2 (p)	43% (.1)		0% (.45)	84% (.01)	0% (.78)
Li et al (2013) ⁵					
Total N	N=434	NR	N=197	N=145	N=288 (experiencing any adverse event)
MD/SMD (95% CI)	15.10 (9.08 to 21.13)		4.55 (-2.23 to 11.32)	0.09 (-0.36 to 0.54)	RR 1.17 (0.72 to 1.92)
NNT (95% CI)	2 (1 to 6)		Not statistically significant	Not statistically significant	Not statistically significant

CI: confidence interval; MD: mean difference; NNT: number needed to treat; NR: not reported; RR: risk ratio; SMD: standardized mean difference.

Subsection Summary: Electric Versus Electromagnetic Stimulation.

Results from three systematic reviews have reached somewhat different conclusions on use of electric and electromagnetic field stimulation for treating knee OA. There was no significant difference between active and sham groups for at least one outcome of interest in all reviews. Studies had a high-risk of bias as well as inadequacies in reporting and validity. Overall, the evidence is insufficient that use of electrical stimulation therapies improve health outcomes.

Pulsed Electrical Stimulation

Randomized Controlled trials

Fary et al (2011) reported on 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. In the placebo group, the device turned itself off after 3 minutes. There were no statistically significant differences between the groups in terms of pain, Western Ontario and McMaster University Arthritis Index (WOMAC) scores, or 36-Item Short-Form Health Survey (SF-36) scores.

Garland et al (2007) reported on a randomized, double-blind, sham-controlled study of the BioniCare device for 58 patients with osteoarthritis of the knee.⁶ Due to protocol violations from 1 of the centers (other new treatments were provided during the study), 42 subjects were excluded from the analysis. At the end of 3 months of use, improvements in pain and WOMAC scores were statistically significantly greater in the active device group than in the sham group.

In their pivotal trial, Zizic et al (1995) reported on a multicenter, double-blind, randomized, sham-controlled trial of pulsed electrical stimulation to assess pain relief and functional improvements in 78 patients with OA of the knee.⁷ Patients in the treatment group used the BioniCare device or placebo group used a dummy device that initially produced a sensation like that of the BioniCare device. Both patient groups were instructed to dial down the level to just below the sensation threshold. In the placebo group, the device would soon 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 patient's condition. Trialists reported the BioniCare group had a statistically significant improvement (defined as improvement $\geq 50\%$) compared with the sham group for each of the primary outcomes assessed.

Subsection Summary: Pulsed Electrical Stimulation

Three RCTs evaluated pulsed electrical stimulation for pain relief and functional improvement in osteoarthritis compared with a sham. Analysis marginally favored pulsed electrical stimulation over placebo.

Pulsed Electromagnetic Field Stimulation

Systematic Review

Tong et al (2022) conducted a systematic review of 11 randomized trials in which patients with osteoarthritis received pulsed electromagnetic fields or control treatment.³¹ Six studies had a sham group and 5 studies used other treatments including hot packs, 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 6 studies, moderate in 2 studies, and low in 3 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 WOMAC scores. Compared to controls, pulsed electromagnetic field stimulation significantly reduced pain (SMD, 0.71; 95% CI, 0.08 to 1.34; $p=.03$; $I^2=93\%$). There were also significant differences in stiffness (SMD, 1.34; 95% CI, 0.45 to 2.23; $p=.003$; $I^2=99\%$) and physical function (SMD, 1.52; 95% CI, 0.49 to 2.55; $p=.004$; $I^2=95\%$) with pulsed electromagnetic field stimulation. All 3 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.

Pulsed Electromagnetic Field Stimulation Versus Sham Treatment

Randomized Controlled Trials

Bagnato et al (2016) reported on a double-blind, sham-controlled trial of 12 hours nightly treatment with a wearable ActiPatch.⁸ 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 the 36-Item Short-Form Health Survey physical scores.

Wuschech et al (2015) evaluated the use of 10-minute daily treatment with the MAGCELL ARTHRO (Physiomed Elektromedizin) in a sham-controlled, double-blind, semi randomized study with 57 patients.⁹ Due to efficacy at interim analysis, only the first 26 patients were randomized. The remainder was assigned to the active treatment group, although patients and assessors remained blinded to treatment allocation. It is unclear whether this study was sufficiently powered, because power analysis indicated that 28 patients would be needed per group. Statistically significant improvements in WOMAC scores were reported by the treatment group compared with the sham group.

Nelson et al (2013) reported on a randomized, double-blind, sham-controlled pilot study with the Palermo device in 34 patients with OA.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. Using intention-to-treat analysis with the last observation carried forward, significant decreases in pain scores were seen at 14 and 42 days. By 6 months, the maximum recorded VAS score decreased by 39% in patients in the active treatment and by 15% in the sham group. The difference in VAS scores between groups (4.19 for pulsed electromagnetic field vs. 6.11 for sham) was statistically and clinically significant. No additional studies with this device have been identified.

Fukada et al (2011) reported a double-blind RCT from South America that included 121 women divided into 4 groups, low (19-minute treatment) or high-dose (38-minute treatment) short-wave electrical field stimulation with a Diatermed II (9 sessions over 3 weeks), placebo, or no-treatment control.¹¹ 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. The percentages 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, in the low-dose group, but not the high-dose group, significant improvement remained on 3 of 5 Knee Osteoarthritis Outcome Score subscales. Because 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.

Pulsed Electromagnetic Field Stimulation Plus Physical Therapy Versus Sham Pulsed Electromagnetic Field Stimulation

Randomized Controlled Trials

de Paula Gomes et al (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).²⁶ Patients were equally allocated into 5 groups (n=20): exercise, exercise + sham, exercise + interferential current therapy (ICT), exercise + pulsed shortwave diathermy therapy (SDT), and exercise + photobiomodulation. Patients received treatment 3 times weekly for a duration of 8 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 8 week treatment period and use of analgesics was not controlled in the study.

Dundar et al (2016) reported on a double-blind, sham-controlled randomized trial of 40 patients with knee OA that evaluated 20 minutes of pulsed electromagnetic field (PMT Quattro PRO; ASA) plus 1 hour of physical therapy (including hot pack, ultrasound, transcutaneous nerve stimulation, and isometric knee exercise), and 20 minutes of sham pulsed electromagnetic field plus 1 hour of the same physical therapy regimen.¹² Both groups-pulsed electromagnetic field plus physical therapy and sham pulsed electromagnetic field plus physical therapy-showed equally significant reductions in pain scores.

Ozguclu et al (2010) reported a double-blind randomized controlled trial from Turkey investigating the effect of pulsed electromagnetic field plus physical therapy in 40 patients with knee osteoarthritis.¹³ Patients with an average pain intensity of 40 or more on a 100-mm VAS were randomized to pulsed electromagnetic field plus physical therapy or to sham pulsed electromagnetic field plus physical therapy. Sessions included a 20-minute hot pack application, 5-minute ultrasound application, and 30 minutes of active or sham pulsed electromagnetic field 5 times a week for 2 weeks, along with isometric knee exercises performed at home. After 2 weeks, both groups showed reductions in pain and improvements in function scores on the WOMAC, but between-group differences were not statistically significant.

Subsection Summary: Pulsed Electromagnetic Field Stimulation

A systematic review and individual studies comparing pulsed electromagnetic field with sham treatment showed benefits to the pulsed electromagnetic field devices; however, different devices were used in each trial and most trials were not conducted in the United States. The results from both randomized trials investigating the effect of pulsed electromagnetic field plus physical therapy on patients with osteoarthritis of the knee found that pulsed electromagnetic field as an adjuvant had no incremental benefit for reduction in pain or statistically significant benefit in stiffness and disability in patients. Both studies had short follow-up windows and long-term benefit of continued therapy cannot be ascertained at this time. Studies with longer periods of follow-up are needed to evaluate the efficacy of pulsed electromagnetic field therapy for osteoarthritis of the knee.

SUMMARY OF EVIDENCE

For individuals who have arthritis who receive pulsed electrical or electromagnetic stimulation, the evidence includes systematic reviews and a number of small randomized controlled trials RCTs. Relevant outcomes are symptoms, functional outcomes, health status measures, and treatment-related morbidity. A review of the literature did not find adequate evidence that use of pulsed electrical or electromagnetic stimulation for the treatment of arthritis improves health outcomes. A 2020 meta-analysis identified 15 randomized sham-controlled trials on treatment

of osteoarthritis of the knee. There was some evidence of clinically and statistically significant improvement in pain, but no evidence of clinically significant improvement in stiffness, function, or quality of life. These conclusions are limited by methodologic shortcomings and inconsistent trial results. Variable results seen in more recent RCTs might also be related to the different devices and treatment durations used. Additional studies with larger numbers of subjects are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Currently ongoing and unpublished trials that may influence this review are listed in Table 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT05151432	Combined Effect of Pulsed Electromagnetic Field and Pulsed Ultrasound Therapy in Treating Knee Osteoarthritis	80	Jul 2022
NCT04197284	Comparison of Efficacy of Biofeedback, Electrical Stimulation and Therapeutic Exercise in Patients With Knee Osteoarthritis (BFBOA)	93	Jun 2022
NCT05315297	Pulsed Electromagnetic Field (PEMF) Therapy in Thumb CMC Arthritis	60	Dec 2023 (not yet recruiting)
NCT05442697	Pulsed Electromagnetic Fields (PEMF) in Knee Osteoarthritis: a Double-blind, Placebo-controlled, Randomised Clinical Trial	240	Dec 2023 (recruiting)
NCT05548712	A Double-Blinded, Randomized-Control-Trial to Investigate the Effect of Pulsed Electromagnetic Field (PEMF) for Patients With Knee Osteoarthritis	80	Sept 2024 (recruiting)
NCT05550428	The Effects of Pulsed Electromagnetic Field Therapy on Patients With End-stage of Knee Osteoarthritis With Sarcopenia: A Double-blinded Randomized Control Trial	60	Jun 2025 (recruiting)
<i>Unpublished</i>			
NCT03542955 ^a	The Efficacy/Safety Profile Of Pulsed Shortwave Therapy in Cervical Osteoarthritis: A	180	Jul 2019 (completed)

	Comparison Study Against Etoricoxib		
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NCT: national clinical trial

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Osteoarthritis Research Society International (OARSI)

In 2019, the Osteoarthritis Research Society International published evidence-based consensus guidelines for nonsurgical management of knee, hip, and polyarticular osteoarthritis.²⁷ Sixty treatment modalities were evaluated for 3 patient groups: knee only, 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. Electromagnetic therapy was considered "strongly recommended against" for all groups due to low quality evidence and an implausible biological mechanism.

American Academy of Orthopaedic Surgeons

In 2021, the American Academy of Orthopaedic Surgeons published updated guidelines on the treatment of osteoarthritis of the knee.²⁸ The guidelines noted that there was only 1 study "that examined the use of a wearable pulsed electromagnetic field device for pain management in subjects with knee osteoarthritis."⁸ 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.²⁸

American College of Rheumatology (ACR)

In 2019, the American College of Rheumatology released guidelines for the management of osteoarthritis of the hand, hip, and knee.²⁹ The guidelines do not mention pulsed electrical or electromagnetic stimulation, but they recommend against transcutaneous electrical stimulation for patients with knee and/or hip osteoarthritis.

In 2021, the American College of Rheumatology released updated recommendations for the treatment of rheumatoid arthritis.³⁰ All recommended treatments were pharmacologic. Use of electrical stimulation for treating rheumatoid arthritis was not addressed

Government Regulations

National/Local:

There is no national coverage determination on this topic. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

CGS Administrators, LLC

Local Coverage Determination (LCD): Transcutaneous Electrical Joint Stimulation Devices (TEJSD) (L34821); effective on or after 01/01/2020

INDICATIONS

There is insufficient published clinical evidence to establish that treatment with TEJSD (HCP code E0762) meets the requirements to be considered reasonable and necessary for the treatment of osteoarthritis or any other condition. Claims for TEJSD (code E0762) will be denied as not reasonable and necessary.

There is insufficient published clinical evidence to establish that treatment with other electro-magnetic devices such as transcutaneous electrical stimulation devices (TENS), neuromuscular stimulators (NMES), functional electrical stimulators (FES), light treatment devices (any type), infrared treatment devices (any type), etc. (not all-inclusive), singly or in any combination, meet the requirements to be considered reasonable and necessary for the treatment of osteoarthritis. Claims for these items will be denied as not reasonable and necessary.

TEJSD COMBINED WITH AN ORTHOSIS (Brace)

TEJSD is currently supplied as a stand-alone device or for use concurrently or in combination with a brace. Braces are separate DMEPOS items with independent coverage requirements that are unrelated to the coverage of TEJSD. When TEJSD is used concurrently or in combination with any type of brace, there no reimbursement possible for the TEJSD device. Refer to the applicable LCD and related Policy Article for information about the payment requirements for reimbursement of braces.

ACCESSORIES / SUPPLIES

Claims for supplies used with a base item are not payable when the base item is not covered. Since code E0762 is not considered to be reasonable and necessary (see above), claims for codes A4465, A4495, A4557, and A4595 to be used with code E0762 will be denied as not reasonable and necessary.

There is no evidence of effectiveness of a TEJSD (E0762) when used with a conductive garment (E0731). Claims for code E0731 billed for use with an E0762 will be denied as not reasonable and necessary.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through June 1, 2023, the date the research was completed.

BCN Medical Policy History

Date	Rationale
10/28/08	BCN policy established
9/23/09	Routine maintenance
5/18/11	Policy title changed from “Electrical/Electromagnetic Stimulation for the Treatment of Arthritis” to “Transcutaneous Electrical Joint Stimulation for the Treatment of Arthritis.” Added Cochrane review reference. Policy status unchanged
8/15/12	Policy titles changed from “Transcutaneous Electrical Joint Stimulation for the Treatment of Arthritis” to “Electrical Stimulation for the Treatment of Arthritis” to match BCBSA policy. References verified. No change in policy status.
8/21/13	Routine review. No change in policy status.
7/16/14	Routine review. Additional devices added, added new rationale. No change in policy status.
8/19/15	Routine review. Additional devices added, added new rationale. No change in policy status.
8/17/16	Routine policy maintenance. Updated rationale and references. Updated summary to reflect new information. MDCH changed to MDHHS. Current clinical trial information added.
8/23/17	Updated rationale, references, clinical trials, supplemental data sections as well as the Medicare coverage section. No change in policy status.
7/18/18	Routine policy maintenance, no changes in policy status.
7/17/19	Removed Medicaid section. Updated rationale, no reference additions/deletions. No change in policy status.
7/9/20	Routine policy maintenance, no change in policy status.
7/15/21	Routine policy maintenance, no change in policy status.
7/7/22	Routine policy maintenance, no change in policy status.
7/13/23	Routine policy maintenance, no change in policy status. Vendor: Northwood. (ky)

Next Review:

3rd Qtr. 2024

**MEDICAL POLICY TITLE: ELECTRICAL STIMULATION FOR THE TREATMENT OF ARTHRITIS
BCN BENEFIT ADMINISTRATION**

I. Coverage Determination

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinurance covered if primary Medicare covers the service

II. Administrative Guidelines

N/A