1.01.27 Electrical and Electromagnetic Stimulation for the Treatment of Arthritis			
Original Policy Date:	July 31, 2015	**Effective Date:**	May 1, 2023
Section:	1.0 Durable Medical Equipment	**Page:**	Page 1 of 14

Policy Statement

I. Electrical or electromagnetic stimulation is considered **investigational** for the treatment of osteoarthritis or rheumatoid arthritis.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

- N/A

Description

Pulsed electrical and electromagnetic stimulation are being investigated to improve functional status and relieve pain related to osteoarthritis and rheumatoid arthritis that is unresponsive to other standard therapies. Electrical stimulation is provided using a device that noninvasively delivers a subsensory, low-voltage, monophasic electrical field to the target site of pain. Pulsed electromagnetic fields are delivered using coils placed over the skin.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

The BioniCare 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 BioniCare 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 radiofrequency 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 short-wave 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 called Torino II, 912-M10, and Roma3™; Ivivi Health Sciences, renamed Amp Orthopedics) was cleared for marketing by the FDA through the 510(k) process as a short-wave diathermy device that applies 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 the 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.

Rationale

Background

Electrical and electromagnetic stimulation are being investigated to improve functional status and to relieve pain related to osteoarthritis and rheumatoid arthritis that are 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 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. It is proposed that the device treats the underlying cause of the disease by stimulating the joint tissue and improving the overall health of the joint and that it provides a slow-acting, but longer-lasting improvement in symptoms. Therefore, pulsed electrical stimulation is proposed to be similar to bone stimulator therapy for fracture nonunion

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 quality and credibility. To be relevant,

studies must represent 1 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. Randomized controlled trials 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.

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 and rheumatoid arthritis?

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

Populations

The relevant population of interest is individuals with osteoarthritis 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, nonsteroidal anti-inflammatory drugs (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 1 year. While studies described below all reported at least 1 outcome of interest, 6 to 12 months duration of follow-up is desirable to assess outcomes.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

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

Review of Evidence

Electrical Versus Electromagnetic Stimulation

Systematic Reviews

Three systematic reviews have reached somewhat different conclusions on the use of electrical 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. 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 and pulsed electromagnetic field for the treatment of knee osteoarthritis.[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 improved with pulsed electrical stimulation and pulsed electromagnetic field, with an SMD 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 of pulsed electrical stimulation and pulsed electromagnetic field for treating osteoarthritis included 9 studies published between 1993 and 2013.[5,] Meta-analyses found that patients randomized to pulsed electrical stimulation or pulsed electromagnetic field rated their pain relief as better than sham-treated patients by 15.10 points more (95% CI, 9.08 to 21.13; absolute improvement, 15%) on a scale of 0 to 100, but found no statistically significant effect for physical 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,]	●		●
Trock et al (1994)[15,]	●	●	●
Jacobson et al (2001)[16,]	●		
Pipitone et al (2001)[17,]	●	●	●
Thamsborg et al (2005)[18,]	●	●	●
Sutbeyaz et al (2006)[19,]	●		
Ay et al (2009)[20,]	●	●	
Kulcu et al (2009)[21,]	●		
Ozguclu et al (2010)[13,]	●	●	
Moldovan et al (2012)[22,]	●		
Pavlovic et al (2012)[23,]	●		
Kanat et al (2013)[24,]	●		
Nelson et al (2013)[10,]	●		●
Wuschech et al (2015)[9,]	●		
Bagnato et al (2016)[8,]	●		
Dundar et al (2016)[12,]	●		
Garland et al (2007)[6,]		●	●
Fary et al (2011)[4,]		●	●
Nicolakis et al (2002)[25,]			●
Zizic et al (1995)[7,]			●

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 confirmation (or both) of osteoarthritis receiving any type of pulsed electromagnetic field or pulsed electrical stimulation	636 (27-167)	RCT	Treatment time: 4 or more weeks

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	N=179	
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)	1.49 (-0.06 to 3.04)	
I^2 (p)	90% (<.00001)	53% (.05)	63% (.009)	95% (<.00001)	
Negm et al (2013)[3,]					

Study	Pain	Stiffness	Physical Function	Quality of Life	Adverse Event
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)
I^2 (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: Electrical Versus Electromagnetic Stimulation

Results from 3 systematic reviews reached somewhat different conclusions on the use of electrical and electromagnetic field stimulation for treating knee osteoarthritis. There was no significant difference between active and sham groups for at least 1 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 the use of electrical stimulation therapies improves 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 transcutaneous electrical nerve stimulation (TENS) unit (Metron Digi-10s) 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 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 study, 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 osteoarthritis of the knee.[7,] Patients in the treatment group used the BioniCare device and the 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 ≥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.[26] 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 minutes of daily treatment with the Magcell Arthro (Physiomed Elektromedizin) in a sham-controlled, double-blind, semi-randomized study with 57 patients with osteoarthritis.[9] Due to efficacy at the interim analysis, only the first 26 patients were randomized. The remainder were 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 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. Using an 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.

Fukuda et al (2011) reported on a double-blind RCT from South America that included 121 women with osteoarthritis 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 the Knee Osteoarthritis Outcome Score subscales. The percentages of patients who attained the minimal clinically important difference of 2 points on the numeric rating scale were 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, larger improvements in the Knee Osteoarthritis Outcome Score subscales were maintained by patients in the pulsed electromagnetic

field groups. Because there was a 36% dropout rate (from patients lost to follow-up, patients who received other therapies, patients who had 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).[27,] 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 osteoarthritis 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 RCT 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.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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

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.

Osteoarthritis Research Society International

In 2019, the Osteoarthritis Research Society International published updated evidence-based consensus guidelines for the nonsurgical management of knee, hip, and polyarticular osteoarthritis.[31,] Sixty treatment modalities were evaluated for 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

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

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
Ongoing			
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

NCT No.	Trial Name	Planned Enrollment	Completion Date
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)
Unpublished			
NCT03542955[a]	The Efficacy/Safety Profile Of Pulsed Shortwave Therapy in Cervical Osteoarthritis: A Comparison Study Against Etoricoxib	180	Jul 2019 (completed)

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

References

1. Department of Health & Human Services. Correction to substantially equivalent letter of June 6, 2003 for BionicCare Stimulator. June 8, 2006. https://www.accessdata.fda.gov/cdrh_docs/pdf3/K030332.pdf. Accessed January 19, 2023.
2. Yang X, He H, Ye W, et al. Effects of Pulsed Electromagnetic Field Therapy on Pain, Stiffness, Physical Function, and Quality of Life in Patients With Osteoarthritis: A Systematic Review and Meta-Analysis of Randomized Placebo-Controlled Trials. Phys Ther. Jul 19 2020; 100(7): 1118-1131. PMID 32251502
3. Negm A, Lorbergs A, Macintyre NJ. Efficacy of low frequency pulsed subsensory threshold electrical stimulation vs placebo on pain and physical function in people with knee osteoarthritis: systematic review with meta-analysis. Osteoarthritis Cartilage. Sep 2013; 21(9): 1281-9. PMID 23973142
4. Fary RE, Carroll GJ, Briffa TG, et al. The effectiveness of pulsed electrical stimulation in the management of osteoarthritis of the knee: results of a double-blind, randomized, placebo-controlled, repeated-measures trial. Arthritis Rheum. May 2011; 63(5): 1333-42. PMID 21312188
5. Li S, Yu B, Zhou D, et al. Electromagnetic fields for treating osteoarthritis. Cochrane Database Syst Rev. Dec 14 2013; (12): CD003523. PMID 24338431
6. Garland D, Holt P, Harrington JT, et al. A 3-month, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of a highly optimized, capacitively coupled, pulsed electrical stimulator in patients with osteoarthritis of the knee. Osteoarthritis Cartilage. Jun 2007; 15(6): 630-7. PMID 17303443
7. Zizic TM, Hoffman KC, Holt PA, et al. The treatment of osteoarthritis of the knee with pulsed electrical stimulation. J Rheumatol. Sep 1995; 22(9): 1757-61. PMID 8523357
8. Bagnato GL, Miceli G, Marino N, et al. Pulsed electromagnetic fields in knee osteoarthritis: a double blind, placebo-controlled, randomized clinical trial. Rheumatology (Oxford). Apr 2016; 55(4): 755-62. PMID 26705327
9. Wuschech H, von Hehn U, Mikus E, et al. Effects of PEMF on patients with osteoarthritis: Results of a prospective, placebo-controlled, double-blind study. Bioelectromagnetics. Dec 2015; 36(8): 576-85. PMID 26562074
10. Nelson FR, Zvirbulis R, Pilla AA. Non-invasive electromagnetic field therapy produces rapid and substantial pain reduction in early knee osteoarthritis: a randomized double-blind pilot study. Rheumatol Int. Aug 2013; 33(8): 2169-73. PMID 22451021
11. Fukuda TY, Alves da Cunha R, Fukuda VO, et al. Pulsed shortwave treatment in women with knee osteoarthritis: a multicenter, randomized, placebo-controlled clinical trial. Phys Ther. Jul 2011; 91(7): 1009-17. PMID 21642511

12. Dündar Ü, Aşık G, Ulaşlı AM, et al. Assessment of pulsed electromagnetic field therapy with Serum YKL-40 and ultrasonography in patients with knee osteoarthritis. Int J Rheum Dis. Mar 2016; 19(3): 287-93. PMID 25955771
13. Ozgüçlü E, Cetin A, Cetin M, et al. Additional effect of pulsed electromagnetic field therapy on knee osteoarthritis treatment: a randomized, placebo-controlled study. Clin Rheumatol. Aug 2010; 29(8): 927-31. PMID 20473540
14. Trock DH, Bollet AJ, Dyer RH, et al. A double-blind trial of the clinical effects of pulsed electromagnetic fields in osteoarthritis. J Rheumatol. Mar 1993; 20(3): 456-60. PMID 8478852
15. Trock DH, Bollet AJ, Markoll R. The effect of pulsed electromagnetic fields in the treatment of osteoarthritis of the knee and cervical spine. Report of randomized, double blind, placebo controlled trials. J Rheumatol. Oct 1994; 21(10): 1903-11. PMID 7837158
16. Jacobson JI, Gorman R, Yamanashi WS, et al. Low-amplitude, extremely low frequency magnetic fields for the treatment of osteoarthritic knees: a double-blind clinical study. Altern Ther Health Med. 2001; 7(5): 54-64, 66-9. PMID 11565402
17. Pipitone N, Scott DL. Magnetic pulse treatment for knee osteoarthritis: a randomised, double-blind, placebo-controlled study. Curr Med Res Opin. 2001; 17(3): 190-6. PMID 11900312
18. Thamsborg G, Florescu A, Oturai P, et al. Treatment of knee osteoarthritis with pulsed electromagnetic fields: a randomized, double-blind, placebo-controlled study. Osteoarthritis Cartilage. Jul 2005; 13(7): 575-81. PMID 15979009
19. Sutbeyaz ST, Sezer N, Koseoglu BF. The effect of pulsed electromagnetic fields in the treatment of cervical osteoarthritis: a randomized, double-blind, sham-controlled trial. Rheumatol Int. Feb 2006; 26(4): 320-4. PMID 15986086
20. Ay S, Evcik D. The effects of pulsed electromagnetic fields in the treatment of knee osteoarthritis: a randomized, placebo-controlled trial. Rheumatol Int. Apr 2009; 29(6): 663-6. PMID 19015858
21. Kulcu DG, Gulsen G, Altunok EC. Short-term efficacy of pulsed electromagnetic field therapy on pain and functional level in knee osteoarthritis: a randomized clinical study. Turk J Rheumatol. 2009;24(3):144-148.
22. Moldovan I, Dita R, Pop L. The effects of focused pulsed electromagnetic field therapy in patients with knee osteoarthritis. A randomized, placebo-controlled study. Palestrica of the Third Millenium Civilization and Sport. 2012;13:91-95.
23. Pavlović AS, Djurasić LM. The effect of low frequency pulsing electromagnetic field in treatment of patients with knee joint osteoarthritis. Acta Chir Iugosl. 2012; 59(3): 81-3. PMID 23654012
24. Kanat E, Alp A, Yurtkuran M. Magnetotherapy in hand osteoarthritis: a pilot trial. Complement Ther Med. Dec 2013; 21(6): 603-8. PMID 24280467
25. Nicolakis P, Kollmitzer J, Crevenna R, et al. Pulsed magnetic field therapy for osteoarthritis of the knee--a double-blind sham-controlled trial. Wien Klin Wochenschr. Aug 30 2002; 114(15-16): 678-84. PMID 12602111
26. Tong J, Chen Z, Sun G, et al. The Efficacy of Pulsed Electromagnetic Fields on Pain, Stiffness, and Physical Function in Osteoarthritis: A Systematic Review and Meta-Analysis. Pain Res Manag. 2022; 2022: 9939891. PMID 35586276
27. de Paula Gomes CAF, Politti F, de Souza Bacelar Pereira C, et al. Exercise program combined with electrophysical modalities in subjects with knee osteoarthritis: a randomised, placebo-controlled clinical trial. BMC Musculoskelet Disord. Apr 20 2020; 21(1): 258. PMID 32312265
28. American Academy of Orthopaedic Surgeons. Management of osteoarthritis of the knee (non-arthroplasty). 2021; https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/oak3cpg.pdf. Accessed January 19, 2023
29. Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. Arthritis Care Res (Hoboken). Feb 2020; 72(2): 149-162. PMID 31908149
30. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). Jul 2021; 73(7): 924-939. PMID 34101387

31. Bannuru RR, Osani MC, Vaysbrot EE, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. Osteoarthritis Cartilage. Nov 2019; 27(11): 1578-1589. PMID 31278997

Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	None	
HCPCS	E0762	Transcutaneous electrical joint stimulation device system, includes all accessories

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
07/31/2015	Policy title change from Electrical Stimulation for Pain and Other Conditions Policy revision with position change. BCBSA Medical Policy adoption
08/01/2016	Policy revision without position change
05/01/2017	Policy revision without position change
05/01/2018	Policy revision without position change
05/01/2019	Policy revision without position change
05/01/2020	Annual review. No change to policy statement. Literature review updated. Policy title changed from Electrical Stimulation for the Treatment of Arthritis to current one.
05/01/2021	Annual review. No change to policy statement. Literature review updated.
06/01/2022	Annual review. No change to policy statement. Literature review updated.
05/01/2023	Annual review. No change to policy statement. Literature review updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished

primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Electrical and Electromagnetic Stimulation for the Treatment of Arthritis 1.01.27 **Policy Statement:** Electrical or electromagnetic stimulation is considered **investigational** for the treatment of osteoarthritis or rheumatoid arthritis.	**Electrical and Electromagnetic Stimulation for the Treatment of Arthritis 1.01.27** **Policy Statement:** I. Electrical or electromagnetic stimulation is considered **investigational** for the treatment of osteoarthritis or rheumatoid arthritis.