Policy Statement

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

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

- Electrical Bone Growth Stimulation of the Appendicular Skeleton
- Transcutaneous Electrical Nerve Stimulation

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 to deliver pulsed electrical stimulation for an adjunctive treatment of osteoarthritis of the knee and rheumatoid arthritis of the hand. The FDA determined that this device was substantially equivalent to transcutaneous electrical nerve stimulation devices. 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- 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 radio frequency 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 over-the-counter use for adjunctive treatment of plantar fasciitis of the heel and osteoarthritis of the knee. FDA product code: PQY.

The Magnetofield® (F&B International, Italy) and Elettronica Pagani (Energy Plus Roland Series, Italy) devices provide pulsed electromagnetic field therapy. They are currently marketed in Europe.

### 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 sub sensory 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 (see Blue Shield of California Medical Policy: Electrical Bone Growth Stimulation of the Appendicular Skeleton).

#### 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 technology, two domains are examined: the relevance, and 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.

**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 PICOTS were used to select literature to inform this review.

**Patients**

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.

**Timing**

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.

**Setting**

Patients with arthritis are actively managed by physical therapists, orthopedic surgeons, and primary care providers in an outpatient clinical setting.

**Study Selection Criteria**

Methodologically credible studies were selected using the following principles:
To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.

In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

To assess longer-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Two systematic reviews have reached somewhat different conclusions on the use of electric and electromagnetic field stimulation for treating knee OA.

A systematic review by Negm et al (2013), which included 7 small, sham-controlled randomized trials (total n=459 patients), examined pulsed electrical stimulation (PES) and pulsed electromagnetic field (PEMF) for the treatment of knee OA. 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) (see next section), 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 PES and 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 confidence intervals around estimates) due to small samples sizes.

A 2013 Cochrane review of PES and PEMF included 9 studies (total n=636 patients) published between 1993 and 2013. Meta-analysis found that patients randomized to PES or PEMF rated their pain relief as better than sham-treated patients by 15.10 points more (95% confidence intervals, 9.08 to 21.13; absolute improvement, 15%) on a scale of 0 to 100 but found no statistically significant effect for function or quality of life. There was a high-risk of bias due to incomplete outcome data in three studies. For all nine studies, there were inadequacies in reporting of study designs and trial conduct, making it unclear whether there was selective outcomes reporting bias.

A number of the trials included in these meta-analyses are described briefly next.

Section Summary: Electric Stimulation Therapies for OA of the Knee

Results from two systematic reviews have reached somewhat different conclusions on use of electric and electromagnetic field stimulation for treating knee OA. In both reviews, there was no significant difference between active and sham groups for at least one outcome of interest. Both 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 (BioniCare)

Randomized Controlled Trials

Fary et al (2011) reported on results from a randomized, double-blind, sham-controlled trial of PES in 70 patients with OA of the knee. The device used in this study was a commercially available transcutaneous electrical nerve stimulation unit (BioniCare) modified to provide PES. In the placebo group, the device turned itself off after three 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 a randomized, double-blind, sham-controlled study of the BioniCare device for 58 patients with OA of the knee. Due to protocol violations from one of the centers (other new treatments were provided during the study), 42 subjects were excluded from the analysis. At the end of three months of use, improvements in pain and WOMAC scores were statistically significantly greater in the active device group than in the sham group.
Zizic et al (1995) reported on a multicenter, double-blind, randomized, sham-controlled trial of PES to assess pain relief and functional improvements in 78 patients with OA of the knee. 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 four 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 statistically significant improvement (defined as improvement ≥50%) compared with the sham group for each of the primary outcomes assessed.

**Nonrandomized Controlled Trials**
Mont et al (2006) reported a nonrandomized study of PES in 157 patients (recruited from 23 centers) with moderate-to-severe knee OA who required total knee arthroplasty (TKA). The time to TKA was compared with a matched (age, sex, weight) historical control group of 101 knee OA patients treated at 1 of the centers. Analysis showed that 60% of patients in the electrical stimulation group had deferred TKA at 4 years compared with 35% in the historical control group. Interpretation was limited due to the potential for higher motivation to avoid TKA in the subjects who participated.

**Uncontrolled Trials**
VQ OrthoCare (2006) published data on 288 patients with knee OA treated with its BioniCare device in an open-label prospective study. Study participants experienced improvements in patient assessment of pain, global evaluation of disease activity, and physician global evaluation of the patient's condition. In addition, 45.4% reduced their use of NSAIDs by 50% or more. However, this study did not include a randomized control group.

**Section Summary: PES (BioniCare)**
Two RCTs evaluated PES for pain relief and functional improvement in OA compared with a sham. Analysis marginally favored PES over placebo. Both trials utilized a sham that turned off automatically. A nonrandomized controlled trial compared time to requirement of TKA in OA patients who had PES compared to an untreated historical control. Deferral of TKA in the intervention group is difficult to interpret. One uncontrolled trial had promising results and reported patients with OA of the knee who were treated with the device had experienced improvements in several clinical areas and reduced their use of NSAIDs by nearly 50%.

**Pulsed Electromagnetic Stimulation**
The literature on PEMF consists primarily of small sample size RCTs using a variety of devices and ranges of treatment times (10 minutes to 12 hours). Most studies were conducted outside of the United States.

**PEMF versus Sham PEMF**
Bagnato et al (2016) reported on a double-blind, sham-controlled trial of 12 hours nightly treatment with a wearable ActiPatch. Sixty-six patients with OA were randomized and 60 completed the trial. Patients in the treatment group showed statistically significant improvements in pain, WOMAC scores, and the 36-Item Short-Form Health Survey physical scores.

Wuschetch et al (2015) evaluated 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 OA. Due to efficacy at the 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. In addition to having knee pain with confirmed articular cartilage loss and an initial visual analog scale (VAS) score of four or more, only patients who had at least two hours of daily standing activity in a physical occupation were included in the study. Using intention-to-treat analysis with 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 PEMF 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 OA 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. Except for the untreated controls, both patients and the physical therapist evaluator were blinded throughout the one-year follow-up. When measured immediately after treatment, both the low- and high-dose groups showed significantly greater improvement than the control groups in the numeric rating scale and the Knee Osteoarthritis Outcome Score subscale scores. 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 one-year follow-up, larger improvements in the Knee Osteoarthritis Outcome Score subscales were maintained by patients in the PEMF 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.

**PEMF Plus Physical Therapy versus Sham PEMF Plus Physical Therapy**

Dundar et al (2016) reported a double-blind, sham-controlled randomized trial of 40 patients with knee OA that evaluated 20 minutes of PEMF plus 1 hour of physical therapy, and 20 minutes of sham PEMF plus 1 hour of physical therapy. Both groups—PEMF (PMT Quattro PRO; ASA) plus physical therapy and sham PEMF 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 PEMF plus physical therapy in 40 patients with knee OA. Patients with an average pain intensity of 40 or more on a 100-mm VAS were randomized to PEMF plus physical therapy or to sham PEMF plus physical therapy. Sessions included a 20-minute hot pack application, 5-minute ultrasound application, and 30 minutes of a active or sham PEMF 5 times a week for 2 weeks, along with isometric knee exercises performed at home. After two weeks, both groups showed reductions in pain and improvements in function scores on the WOMAC but between-group differences were not statistically significant.

**Section Summary: PEMF plus Physical Therapy versus Sham PEMF plus Physical Therapy**

The results from both randomized trials investigation of the effect of PEMF plus physical therapy in patients with OA of the knee found that PEMF 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 PEMF therapy for OA of the knee.

**Summary of Evidence**

For individuals who have arthritis who receive pulsed electrical or electromagnetic stimulation, the evidence includes a number of small RCTs. The 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 2013 meta-analysis identified 9
randomized sham-controlled trials on treatment of OA of the knee. There was some evidence of improved function but no evidence of reduced pain. These conclusions are limited by methodologic shortcomings and inconsistent trial results. More recent RCTs have also had variable results, which might 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 the effects of the technology on health outcomes.

**Supplemental Information**

**Practice Guidelines and Position Statements**

**Osteoarthritis Research Society International**
The Osteoarthritis Research Society International (2014) published evidence-based consensus guidelines for nonsurgical management of knee osteoarthritis (OA). Twenty-nine treatment modalities were evaluated for four patient groups: knee-only OA, knee-only OA with comorbidities, multi-joint OA, and multi-joint OA with comorbidities. Neuromuscular electrical stimulation was considered "not appropriate" for all four groups. Evidence consisted of a systematic review and meta-analysis of randomized controlled trials. The quality of the evidence was considered fair.

**American Academy of Orthopaedic Surgeons**
The American Academy of Orthopaedic Surgeons (2013) published guidelines on the treatment of OA of the knee. Due to the overall inconsistent finding for electrotherapeutic modalities, the Academy did not recommend for or against use in patients with symptomatic knee OA. The strength of the recommendation was inconclusive.

**American College of Rheumatology**
The American College of Rheumatology published recommendations on the use of nonpharmacologic and pharmacologic therapies for OA. The recommendations were classified as either "strong," "conditional," or "none." The College issued a conditional recommendation for the use of transcutaneous electrical stimulation for the treatment of OA of the knee. This recommendation should only be considered for patients with chronic moderate or severe pain who are candidates for total knee arthroplasty but who are unwilling or unable to undergo the procedure due to comorbidities or concomitant use of medications that are contraindications to surgery or are advised against the procedure by a surgeon. Updated guidelines are expected in 2018.

The College (2015) released recommendations for the treatment of rheumatoid arthritis. All recommended treatments were pharmacologic. Use of electrical stimulation for treating rheumatoid arthritis was not addressed. Updated guidelines are expected in 2019 or early 2020.

**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 1.

**Table 1. Summary of Key Trials**

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<th>Trial Name</th>
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<th>Completion Date</th>
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<td>Ongoing</td>
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**References**


**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. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

**IE**

The following services may be considered investigational.

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<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tr>
<td>HCPCS</td>
<td>E0762</td>
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<tr>
<td>ICD-10 Procedure</td>
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<td>Transcutaneous electrical joint stimulation device system, includes all accessories</td>
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**Policy History**

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

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<td>Policy title change from Electrical Stimulation for Pain and Other Conditions</td>
<td>Medical Policy Committee</td>
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<td>Policy revision with position change</td>
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<td>BCBSA Medical Policy adoption</td>
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<td>08/01/2016</td>
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**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not
investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**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 (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. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

**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.