LifeWise
Health Plan of Washington

MEDICAL POLICY – 1.01.27

Electrical and Electromagnetic Stimulation for the Treatment of Arthritis

BCBSA Ref. Policy:	1.01.27	
Effective Date:	June 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	May 13, 2024	1.01.507 Electrical Stimulation Devices
Replaces:	N/A	7.01.07 Electrical Bone Growth Stimulation of the Appendicular Skeleton

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Arthritis is inflammation of the joints that can cause pain, stiffness, and swelling. One type of arthritis is called osteoarthritis (OA), or "wear and tear" arthritis. This happens when the protective tissue around bones breaks down over time. Rheumatoid arthritis (RA) is another type of arthritis. It occurs when the body's immune system attacks the protective tissues around joints. Prescription drugs, physical therapy, and shots in the joints are a common way to treat arthritis. Electric and electromagnetic stimulation are other possible methods to treat arthritis and reduce pain. They are noninvasive and use devices to deliver low-level electrical or electromagnetic pulses through the skin. The use of electric or electromagnetic stimulation to treat osteoarthritis or rheumatoid arthritis is unproven (investigational). More studies are needed to see if this type of treatment improves health outcomes.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

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

Coding

Code	Description
HCPCS	
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

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.

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 (see **Related Policies**).

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 1**.

Table 1. 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
NCT05315297	Pulsed Electromagnetic Field (PEMF) Therapy in Thumb CMC Arthritis	60	Dec 2024(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)
NCT04197284	Comparison of Efficacy of Biofeedback, Electrical Stimulation and Therapeutic Exercise in Patients With Knee Osteoarthritis (BFBOA)	93	Jun 2022 (unknown status)
NCT05151432	Combined Effect of Pulsed Electromagnetic Field and Pulsed Ultrasound Therapy in Treating Knee Osteoarthritis	80	Jul 2022 (completed)

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

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion 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.[29] The guidelines noted that there was only one 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.[29]

American College of Rheumatology

In 2019, the American College of Rheumatology released guidelines for the management of osteoarthritis of the hand, hip, and knee.[30] 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.[31] 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.[32] Sixty treatment modalities were evaluated for three 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.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

The BioniCare Bio-1000 stimulator (VQ OrthoCare) was cleared for marketing by the 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 policy.

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History

Date	Comments
06/01/22	New policy, approved May 10, 2022. Electrical or electromagnetic stimulation is considered investigational for the treatment of osteoarthritis or rheumatoid arthritis.
06/01/23	Annual Review, approved May 5, 2023. Policy updated with literature review through January 13, 2023; reference added. Policy statement unchanged.
06/01/24	Annual Review, approved May 13, 2024. Policy updated with literature review through January 22, 2024; reference added. Policy statement unchanged.

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