PREMERA | BLUE CROSS

An Independent Licensee of the Blue Cross Blue Shield Association

MEDICAL POLICY – 1.01.27

Electrical and Electromagnetic Stimulation for the Treatment of Arthritis

BCBSA Ref. Policy:	1.01.27	
Effective Date:	Jun. 1, 2025	RELATED MEDICAL POLICIES:
Last Revised:	May 12, 2025	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

Clicking this icon returns you to the hyperlinks menu above.

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			
NCT05442697	Pulsed Electromagnetic Fields (PEMF) in Knee Osteoarthritis: a Double-blind, Placebo-controlled, Randomised Clinical Trial	240	Dec 2024 (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
Unpublished			
NCT05315297	Pulsed Electromagnetic Field (PEMF) Therapy in Thumb CMC Arthritis	60 (actual)	Aug 2024 (actual)
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 (actual)	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.

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 April 15, 2025.
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. Yabroudi MA, Aldardour A, Nawasreh ZH, et al. Effects of the combination of pulsed electromagnetic field with progressive resistance exercise on knee osteoarthritis: A randomized controlled trial. J Back Musculoskelet Rehabil. 2024; 37(1): 55-65. PMID 37718773

28. 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

29. 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 April 15, 2025.

30. 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

31. 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

32. 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

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.
06/01/25	Annual Review, approved May 12, 2025. Policy updated with literature review through January 22, 2025; no references added. Policy statement unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.