



FEP Medical Policy Manual

FEP 1.01.27 Electrical and Electromagnetic Stimulation for the Treatment of Arthritis

Effective Policy Date: July 1, 2022

Original Policy Date: September 2012

Related Policies:

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

Electrical and Electromagnetic Stimulation for the Treatment of Arthritis

Description

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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.

OBJECTIVE

The objective of this evidence review is to evaluate whether use of pulsed electrical or electromagnetic stimulation improves net health outcomes better than standard therapies (pharmacologic and physical) in patients with pain related to osteoarthritis and rheumatoid arthritis.

POLICY STATEMENT

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

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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. FDA product code: PQY.

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

Transcutaneous electrical nerve stimulation devices are evaluated in policy review 1.01.09.

RATIONALE

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.

SUPPLEMENTAL INFORMATION

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.

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.²⁷ Sixty treatment modalities were evaluated for 3 patient groups: knee-only, hip, and multijoint osteoarthritis. Neuromuscular electrical stimulation was considered "strongly recommended against" for all groups due to low quality evidence from trials with small sample sizes and insufficient duration of follow-up. Electromagnetic therapy was considered "strongly recommended against" for all groups due to low quality evidence and an implausible biological mechanism.

American Academy of Orthopaedic Surgeons

In 2021, the American Academy of Orthopaedic Surgeons published updated guidelines on the treatment of osteoarthritis of the knee.²⁸ The guidelines noted that there was only 1 study "that examined the use of a wearable pulsed electromagnetic field device for pain management in subjects with knee osteoarthritis."⁸ The strength of recommendation was downgraded to "limited" from inconclusive since there is only this single "moderate" quality study recommending for or against the intervention.²⁸

American College of Rheumatology

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.

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.

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 18, 2022.
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. Dundar U, Asik G, Ulasli 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. Ozguclu 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.* Sep-Oct 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. Pavlovic AS, Djurasic 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. 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
27. Bannuru RR, Osani MC, Vaysbrot EE, et al. OARSJ guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. *Osteoarthritis Cartilage.* Nov 2019; 27(11): 1578-1589. PMID 31278997
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 18, 2022
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

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2012	New policy	
March 2014	Replace policy	Literature reviewed and updated with references 7-9 added The policy statement is unchanged.
March 2015	Replace policy	Policy updated with literature review, references 1, 3, and 13 were added. The policy statement is unchanged.
June 2017	Replace policy	Policy updated with literature review through January 25, 2017; references 11-14 and 16-17 added. Policy statement unchanged.
June 2018	Replace policy	Policy updated with literature review through January 8, 2018. Policy statement unchanged except "not medically necessary" corrected to "investigational" due to FDA 510k status.
March 2019	Replace policy	Policy updated with literature review through January 6, 2019; no references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through January 13, 2020; reference added. Policy statements unchanged. Title changed to add electromagnetic stimulation.
June 2021	Replace policy	Policy updated with literature review through December 13, 2020; references added. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through January 18, 2022; references added. Policy statement unchanged.

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