BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 1.01.27 Electrical and Electromagnetic Stimulation for the Treatment of Arthritis

Annual Effective Policy Date: July 1, 2024

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 (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.

Transcutaneous electrical nerve stimulation (TENS) devices are evaluated in 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.

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 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.[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 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.

REFERENCES

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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€š corrected to "investigational€š 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.
June 2023	Replace policy	Policy updated with literature review through January 13, 2023; reference added. Policy statement unchanged.
June 2024	Replace policy	Policy updated with literature review through January 22, 2024; reference added. Policy statement unchanged.