FEP 1.01.27 Electrical Stimulation for the Treatment of Arthritis

Effective Date: July 15, 2018

Related Policies: None
1.01.09 Transcutaneous Electrical Nerve Stimulation
7.01.07 Electrical Bone Growth Stimulation of the Appendicular Skeleton

Electrical Stimulation for the Treatment of Arthritis

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.

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 to deliver pulsed electrical stimulation for 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 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 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 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.

POLICY STATEMENT

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

BENEFIT APPLICATION

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

RATIONALE

Summary of Evidence

For individuals who have arthritis who receive pulsed electrical or electromagnetic stimulation, the evidence includes a number of small randomized controlled trials. 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 osteoarthritis 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 randomized controlled trials 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

In 2014, the Osteoarthritis Research Society International published evidence-based consensus guidelines for nonsurgical management of knee osteoarthritis (OA).[14] Twenty-nine treatment modalities were evaluated for 4 patient groups: knee-only OA, knee-only OA with comorbidities, multijoint OA, and multijoint OA with comorbidities. Neuromuscular electrical stimulation was considered “not appropriate” for all 4 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 published guidelines on the treatment of OA of the knee in 2013.[15] 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

In 2012, the American College of Rheumatology published recommendations on the use of nonpharmacologic and pharmacologic therapies for OA.[16] 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.

In 2015, the College released recommendations for the treatment of rheumatoid arthritis.[17] 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 (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY

Date	Action	Description
September 2012	New Policy	
March 2014	Update Policy	Literature reviewed and updated with references 7-9 added The policy statement is unchanged.
March 2015	Update Policy	Policy updated with literature review, references 1, 3, and 13 were added. The policy statement is unchanged.
June 2017	Update Policy	Policy updated with literature review through January 25, 2017; references 11-14 and 16-17 added. Policy statement unchanged.
June 2018	Update 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.