

Medical Coverage Policy | Electrical Stimulation for Treatment of Arthritis



EFFECTIVE DATE: 04|01|2015

POLICY LAST UPDATED: 01|20|2015

OVERVIEW

Pulsed electrical and electromagnetic stimulation are being investigated to improve functional status and relieve pain related to osteoarthritis (OA) and rheumatoid arthritis (RA) unresponsive to other standard therapies. 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 that are placed over the skin.

PRIOR AUTHORIZATION

Prior authorization review is not required.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial

Electrical stimulation for the treatment of arthritis is considered **not medically necessary** as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

MEDICAL CRITERIA

Not applicable.

BACKGROUND

Electrical stimulation has been used to improve functional status and relieve pain related to osteoarthritis and rheumatoid arthritis 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/electrodes are placed on either side of the knee or wrist.

Electrical stimulation is provided by an electronic device that non-invasively delivers a subsensory low voltage, monophasic electrical field to the target site of pain. Pulsed electromagnetic fields are delivered via treatment coils that are placed over the skin. Combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying magnetic field onto an additional static magnetic field.

The BioniCare Bio-1000™ stimulator is a device that has received U.S. Food and Drug Administration (FDA) 510(k) marketing clearances to deliver pulsed electrical stimulation for the treatment of osteoarthritis of the knee and rheumatoid arthritis of the hand. The FDA gave the BioniCare Bio-1000™ clearance after finding it to be substantially equivalent to transcutaneous electrical nerve stimulation (TENS) devices. The BioniCare system consists of an electronic stimulator device with electrical leads that are placed over the affected area and held in place with a lightweight, flexible wrap and Velcro fasteners. The battery-powered device delivers small pulsed electrical currents of 0.0 to 12.0 volt output. It is recommended that the device be worn for at least 6 hours per day, and patients are reported to often wear the device while sleeping. 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.

The FDA's 510(k) summaries specify the BioniCare Stimulator, Model Bio-1000™ is indicated for use as an adjunctive therapy in reducing the level of pain and:

- symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the physician's global evaluation (clinical studies); and
- stiffness associated with pain from rheumatoid arthritis of the hand.

The BioniCare system is contraindicated in patients with demand-type pacemakers and may interfere with other electronic devices.

The OrthoCor™ Active Knee System (OrthoCor Medical) uses pulsed electromagnetic field energy at a radio frequency of 27.12 MHz to treat pain. The OrthoCor Knee System received marketing clearance from the FDA in 2009 and is classified as a shortwave diathermy device for use other than applying therapeutic deep heat. 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 and are supplied in packets of 15. The predicate devices are the OrthoCor (K091640) and Ivivi Torino II™.

The SofPulse™ (also Torino II, 912-M10, and Roma3™, Ivivi Health Sciences) received marketing clearance in 2008 as short-wave diathermy devices that apply electromagnetic energy at a radio frequency of 27.12 MHz (K070541). They are indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue. Palermo is another name for a device marketed by Ivivi Health Sciences.

A review of the literature has not found adequate evidence to indicate the use of pulsed electrical or electromagnetic stimulation for the treatment of arthritis will result in improvements in health outcomes. Therefore, electrical stimulation for the treatment of arthritis is considered not medically necessary as there is no proven efficacy.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

CODING

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Although there is no code specific to electrical stimulation for the treatment of arthritis E0762 is often used. E0762 is considered **not medically necessary**.

E0762

ICD-9 and ICD-10 diagnosis codes for which CPT code E0762 is considered not medically necessary.



Electrical Stimulation
ICD 9 Dx Codes from



Electrical Stimulation
ICD 10 Dx Codes from

RELATED POLICIES

Not applicable.

PUBLISHED

Provider Update	Apr	2015
Provider Update	Jun	2014
Provider Update	Aug	2013
Provider Update	Sep	2012

Provider Update	Aug 2011
Provider Update	Aug 2010
Provider Update	Sep 2009

REFERENCES

1. NHIC, Corp. Local Coverage Determination (LCD): Transcutaneous Electrical Joint Stimulation Devices (TEJSD) (L28551)
2. Zizic TM, Hoffman KC, Holt PA et al. The treatment of osteoarthritis of the knee with pulsed electrical stimulation. *J Rheumatol* 1995; 22(9):1757-61.
3. Hulme J, Robinson V, DeBie R et al. Electromagnetic fields for the treatment of osteoarthritis. *Cochrane Database Syst Rev* 2002; (1):CD003523.
4. 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* 2007; 15(6):630-7.
5. 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* 2011; 63 (5):1333-42.
6. Caldwell J, Zizic T. Pulsed electrical stimulation (PES) treatment of hand rheumatoid arthritis (RA) improves patient pain, physician global evaluation of disease and patient functional assessment but causes a large placebo effect in tender and swollen joint counts. . *Presentation at American College of Rheumatology Annual Scientific Meeting, November, 2005. Presentation No. 1463; Poster Board No. 239* San Diego, California.
7. Mont MA, Hungerford DS, Caldwell JR et al. Pulsed electrical stimulation to defer TKA in patients with knee osteoarthritis. *Orthopedics* 2006; 29(10):887-92.
8. He DY, Jones LC, Hoffman KC et al. The use of electrical stimulation to avoid total knee arthroplasty *Poster Presentation at American Academy of Orthopaedic Surgeons' 71st Annual Meeting, March 10-14, 2004, Poster Board No. P170* . San Francisco, California.
9. Farr J, Mont MA, Garland D et al. Pulsed electrical stimulation in patients with osteoarthritis of the knee: follow up in 288 patients who had failed non-operative therapy. *Surg Technol Int* 2006; 15:227-33.
10. 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* 2011; 91(7):1009-17.
11. 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* 2010; 29(8):927-31.

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