

# Protocol

## Electrical Stimulation for the Treatment of Arthritis

(10127)

<b>Medical Benefit</b>	<b>Effective Date:</b> 05/01/06	<b>Next Review Date:</b> 01/15
<b>Preatuthorization</b>	No	<b>Review Dates:</b> 05/07, 07/08, 09/09, 03/10, 01/11, 01/12, 01/13, 01/14

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preatuthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

### Description

Sub-sensory pulsed electrical stimulation is one form of electrical stimulation. Pulsed electrical stimulation using surface electrodes is being evaluated for the treatment of arthritis.

### Background

Electrical stimulation has been used to improve functional status and relieve pain related to osteoarthritis and rheumatoid arthritis unresponsive to other standard therapies. Electrical stimulation is provided by an electronic device that noninvasively delivers a sub-sensory low-voltage, monophasic electrical field to the target site of pain. 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. Therefore, pulsed electrical stimulation is proposed to be similar to bone stimulator therapy for fracture nonunion.

### Regulatory Status

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 six hours per day, and patients are reported to often wear the device while sleeping.

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

(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 and are supplied in packets of 15. The predicate devices are the OrthoCor (K091640) and Ivivi Torino II™ (K070541).

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.

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.

#### Related Protocols

Transcutaneous Electrical Nerve Stimulation (TENS)

Electrical Bone Growth Stimulation of the Appendicular Skeleton

#### Policy (Formerly Corporate Medical Guideline)

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

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

#### References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. 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.
2. Hulme J, Robinson V, DeBie R et al. Electromagnetic fields for the treatment of osteoarthritis. *Cochrane Database Syst Rev* 2002; (1):CD003523.
3. 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.
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* 2011; 63(5):1333-42.

5. 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.
6. 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.
7. 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.
8. 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.
9. 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.
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11. 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* 2013; 33(8):2169-73.