

# 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> 01/18
<b>Preauthorization</b>	No	<b>Review Dates:</b> 05/07, 07/08, 09/09, 03/10, 01/11, 01/12, 01/13, 01/14, 01/15, 01/16, 01/17	

***This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.***

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"><li>• With osteoarthritis</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Electrical stimulation</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Pharmacologic therapy</li><li>• Physical therapy</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Symptoms</li><li>• Functional outcomes</li><li>• Health status measures</li><li>• Treatment-related morbidity</li></ul>

### Description

Pulsed electrical and electromagnetic stimulation are being investigated to improve functional status and relieve pain related to osteoarthritis (OA) 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 placed over the skin.

### Summary of Evidence

For individuals who have arthritis who receive electrical stimulation, the evidence includes 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 will improve health outcomes. A 2013 meta-analysis identified nine randomized sham-controlled trials on treatment of OA of the knee. There was some evidence of improved function but no evidence of reduced pain. These conclusions are limited by methodologic shortcomings and inconsistency of trial results. More recent RCTs have also had variable results, which may be related to the different devices used and different durations of treatment. Additional studies with larger numbers of subjects are needed. The evidence is insufficient to determine the effects of the technology on health outcomes.

### Policy

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

## Background

Electrical stimulation is being investigated to improve functional status and to 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 noninvasively delivers a subsensory low-voltage, monophasic electrical field to the target site of pain. Pulsed electromagnetic fields are delivered via treatment coils placed over the skin. Combined magnetic fields deliver a time-varying field by superimposing the time-varying field onto an additional static magnetic field.

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 (see the Electrical Bone Growth Stimulation of the Appendicular Skeleton Protocol).

## 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 the treatment of osteoarthritis of the knee and rheumatoid arthritis of the hand. FDA determined that this device was substantially equivalent to transcutaneous electrical nerve stimulation (TENS) 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 Velcro fasteners. The battery-powered device delivers small pulsed electrical currents of 0.0- to 12.0-V output. It is recommended that the device be worn for at least six hours per day, and can be worn 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.

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. In 2009, the OrthoCor Knee System was cleared for marketing by FDA through the 510(k) process 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).

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. Palermo is a portable battery-operated device.

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

Electrical Bone Growth Stimulation of the Appendicular Skeleton

Transcutaneous Electrical Nerve Stimulation

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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.

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14. American Academy of Orthopaedic Surgeons. Treatment of osteoarthritis of the knee. 2013; <http://www.aaos.org/research/guidelines/guidelineoaknee.asp>. Accessed November 4, 2014.
15. Noridian Healthcare Solutions, LLC, (Connecticut, District of Columbia, Delaware, Massachusetts, Maryland, Maine, New Hampshire, New Jersey, New York - Entire State, Pennsylvania, Rhode Island, Vermont) Local Coverage Determination (LCD): Transcutaneous ELECTRICAL Joint STIMULATION Devices (TEJSD) (L34821), Revision Effective Date for services performed on or after 07/01/2016.