

# 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> 01/21
<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, 01/18, 01/19, 01/20	

***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 arthritis</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Pulsed electrical or electromagnetic 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 and rheumatoid arthritis that is unresponsive to other standard therapies. Electrical stimulation is provided using a device that noninvasively delivers a sub-sensory low-voltage, monophasic electrical field to the target site of pain. Pulsed electromagnetic fields are delivered using coils placed over the skin.

### 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 nine 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.

## POLICY

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

## BACKGROUND

Electrical and electromagnetic stimulation are being investigated to improve functional status and to relieve pain related to osteoarthritis and rheumatoid arthritis that are unresponsive to other standard therapies. Non-invasive 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 or electrodes are placed on either side of the knee or wrist. 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. Pulsed electromagnetic fields are delivered via treatment coils placed over the skin. Combined magnetic fields deliver a time-varying field by superimposing that 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. 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. 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 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 light-weight, 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 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 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.

## 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 and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services 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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