Electrical Stimulation for the Treatment of Arthritis

**Description of Procedure or Service**

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.

**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 6 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.

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® stimulator device 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
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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 IITM (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 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 Policy:
TENS (Transcutaneous Electrical Nerve Stimulator)
Electrical Bone Growth Stimulation

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

Electrical stimulation is considered investigational for the treatment of osteoarthritis or rheumatoid arthritis. BCBSNC does not provide coverage for investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Electrical stimulation for the treatment of arthritis is covered

Not applicable.

When Electrical stimulation for the treatment of arthritis is not covered

Electrical stimulation is considered investigational for the treatment of osteoarthritis or rheumatoid arthritis. BCBSNC does not provide coverage for investigational services.

Policy Guidelines

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 9 randomized sham-controlled trials on treatment of osteoarthritis (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.
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The American Academy of Orthopaedic Surgeons (AAOS) published guidelines on the treatment of OA of the knee in 2013. Due to the overall inconsistent finding for electrotherapeutic modalities, AAOS was unable to recommend for or against use in patients with symptomatic knee OA. The strength of the recommendation was inconclusive.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: E0762

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

From policy entitled: Bionicare Stimulator


Policy Retitled: Electrical Stimulation for the Treatment of Arthritis


Electrical Stimulation for the Treatment of Arthritis


Policy Implementation/Update Information

From policy entitled: Bionicare Stimulator


03/02/06 CPT code E0762 added to Billing/Coding section.

4/9/07 Description of electrical stimulation added for clarity. Statement in Policy Guidelines section was deleted and replaced with the following: A review of the literature has not found adequate evidence to indicate the use of electrical/electromagnetic stimulation for the treatment of arthritis will result in improvements in health outcomes. Only one published study on the use the BioniCare® Stimulator device for osteoarthritis of the knee has been identified. No published studies for rheumatoid arthritis were identified. References updated. Specialty Matched Consultant Advisory Panel review 3/15/07. No changes to policy coverage criteria. (adn)

12/31/07 Typo corrected. (adn)

4/27/09 Routine biennial review. Specialty Matched Consultant Advisory Panel review meeting 3/26/09. No changes made to policy criteria. Policy status changed to: "Active policy, no longer scheduled for routine literature review."

6/22/10 Policy Number(s) removed. (amw)

Policy Re-titled: Electrical Stimulation for the Treatment of Arthritis

10/16/12 Policy re-titled, “Electrical Stimulation for the Treatment of Arthritis” for consistency with BCBSA. Converted to active policy from active archive status. Description section revised. Medical director review 9/2012. No change to policy statement.(lpr)

12/11/12 Reference update added. No change to policy statement. (lpr)

3/12/13 Specialty Matched Consultant Advisory Panel review meeting 2/20/2013. No change to policy statement. (lpr)
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3/11/14 Description section updated. Specialty Matched Consultant Advisory Panel review meeting 2/25/2014. References updated. No change to policy statement. (lpr)

3/10/15 Updated Policy Guidelines. Specialty Matched Consultant Advisory Panel review meeting 2/25/2015. No change to policy statement. Reference added. (lpr)

4/1/16 Specialty Matched Consultant Advisory Panel review 2/24/2016. No change to policy. (an)


Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.