

Corporate Medical Policy

Electrical Stimulation for the Treatment of Arthritis

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| File Name: | electrical_stimulation_for_the_treatment_of_arthritis |
| Origination: | 11/2004 |
| Last CAP Review: | 2/2019 |
| Next CAP Review: | 2/2020 |
| Last Review: | 2/2019 |

Description of Procedure or Service

Pulsed electrical and electromagnetic stimulation are 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. 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.

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 (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 self-adhesive fasteners. The battery-powered device delivers small pulsed electrical currents of 0.0- to 12.0-V output.

The OrthoCor™ Active Knee System (OrthoCor Medical; acquired by Caerus Corp. in 2016) 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, renamed Amp Orthopedics) received marketing clearance in 2008 as short-wave diathermy devices that apply electromagnetic energy at a radio frequency of 27.12 MHz.. 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.

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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.

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.

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.

In 2012, the American College of Rheumatology published recommendations on the use of nonpharmacologic and pharmacologic therapies for OA. The recommendations were classified as either *strong*, *conditional*, or *none*. The college issued a conditional recommendation for the use of transcutaneous electrical stimulation for the treatment of OA of the knee. This

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recommendation should only be considered for patients with chronic moderate or severe pain who are candidates for total knee arthroplasty, but who are unwilling or unable to undergo the procedure due to comorbidities or concomitant use of medications that are contraindications to surgery or are advised against the procedure by a surgeon.

In 2016, the American College of Rheumatology published recommendations for the treatment of rheumatoid arthritis. All recommended treatments were pharmacologic. Use of electrical stimulation for treatment of rheumatoid arthritis was not addressed.

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

BCBSA TEC Assessment [Electronic Version]. January 1997.

ECRI Hotline Response, 5/25/2004. Pulsed electrical stimulation for treatment of OA of the knee. Retrieved on September 27, 2004 from <http://www.ta.ecri.org/Hotline/Prod/summary>.

BCBSA TEC Medical Policy Clearinghouse News [Electronic Version]. October 15, 2004.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 11/09/2004.

Pelland L, Brosseau L, Casimiro L, Robinson VA, Tugwell P, Wells G. Electrical stimulation for the treatment of rheumatoid arthritis. Cochrane Database of Systematic Reviews 2002, Issue 2. Art. No.:CD003687. DOI: 10.1002/14651858.CD003687.

U.S. Food and Drug Administration. 510(k) Summary (June 2003). BioniCare® Stimulator. Retrieved 6/12/06 from <http://www.fda.gov/cdrh/pdf3/k030332.pdf>

California Technology Assessment Forum (October 2005). Interferential Stimulation for the Treatment of Musculoskeletal Pain. Retrieved 6/12/06 from <http://www.ctaf.org/ass/viewfull.ctaf?id=65198186094>

ECRI Target Report #890 (January 2006) Transcutaneous electrical joint stimulation for knee osteoarthritis. Retrieved 6/12/06 from <http://www.target.ecri.org>

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 4/25/06.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 1/10/08.

Policy Retitled: Electrical Stimulation for the Treatment of Arthritis

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 10/4/2011.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 10/11/12.

Specialty Matched Consultant Advisory Panel 2/2013

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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.

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.

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.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 12/12/13.

Specialty Matched Consultant Advisory Panel- 2/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 12/11/14.

Specialty Matched Consultant Advisory Panel- 2/2015

Specialty Matched Consultant Advisory Panel- 2/2016

American Academy of Orthopaedic Surgeons. Treatment of osteoarthritis of the knee. 2013; <http://www.aaos.org/research/guidelines/guidelineoaknee.asp>

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 12/11/14.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 6/16/2016

Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care Res (Hoboken)*. Apr 2012;64(4):465-474. PMID 26545940

Singh JA, Saag KG, Bridges SL, et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*, Jan 2016;68(1):1-26. PMID 26545940. Retrieved 1/10/2018 from:

<https://www.rheumatology.org/Portals/0/Files/ACR%202015%20RA%20Guideline.pdf>

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 3/9/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 3/8/2018

Policy Implementation/Update Information

From policy entitled: Bionicare Stimulator

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| 11/11/04 | New policy issued. BioniCare® stimulators are considered investigational. References added. Notification 11/11/2004. Effective 1/20/2005. |
| 4/7/05 | Specialty Matched Advisory Panel [MPAG] review on 3/10/2005. No changes made to policy criteria. Reference added. |
| 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) |

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- 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)
- 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)
- 3/31/17 Revised Description section. Updated Policy Guidelines. References added. Specialty Matched Consultant Advisory Panel review 2/22/2017. No change to policy statement. (an)
- 3/29/18 New device added to Description section. References added. Specialty Matched Consultant Advisory Panel review 2/28/2018. No change to policy statement. (an)
- 3/12/19 Minor revisions to Description section. Policy Guidelines section updated. References added. Specialty Matched Consultant Advisory Panel review 2/20/2019. No change to policy statement. (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.