Corporate Medical Policy

Electrical Stimulation for the Treatment of Arthritis

File Name: electrical_stimulation_for_the_treatment_of_arthritis
Origination: 11/2004
Last Review: 2/2024

Description of Procedure or Service

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. 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 or 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 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.

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 in 1997 to deliver pulsed electrical stimulation for adjunctive treatment of osteoarthritis of the knee, then later for rheumatoid arthritis of the hand. The FDA originally determined that this device was substantially equivalent to transcutaneous electrical nerve stimulation (TENS) devices. The manufacturer requested reclassification due to the fact that the target tissue is joint tissue, not nerve. In 2006, the FDA reclassified the device as a transcutaneous electrical stimulator for arthritis.1, 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-V 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 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. 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 and Ivivi Torino II™.

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.

In 2017, the ActiPatch® (BioElectronics) was cleared for marketing by the FDA through the 510(k) process for nonprescription use for adjunctive treatment of plantar fasciitis of the heel and osteoarthritis of the knee. FDA product code: PQY. In January 2020, the ActiPatch indications for use were broadened to adjunctive treatment of musculoskeletal pain.

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

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 subsensory, low-voltage, monophasic electrical field to the target site of pain. Pulsed electromagnetic fields are delivered using coils placed over the skin.

For individuals who have arthritis who receive pulsed electrical or electromagnetic stimulation, the evidence includes systematic reviews and 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 improves health outcomes. A 2020 meta-analysis identified 15 randomized sham-controlled trials on treatment of osteoarthritis of the knee. There was some evidence of clinically and statistically significant improvement in pain, but no evidence of clinically significant improvement in stiffness, function, or quality of life. These conclusions are limited by methodologic shortcomings and inconsistent trial results. Variable results seen in more recent RCTs might also 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 that the technology results in an improvement in the net health outcome.

In 2021, the American Academy of Orthopaedic Surgeons published updated guidelines on the treatment of osteoarthritis of the knee. The guidelines noted that there was only 1 study "that examined the use of a wearable pulsed electromagnetic field device for pain management in subjects with knee osteoarthritis." The strength of recommendation was downgraded to "limited" from inconclusive since there is only this single "moderate" quality study recommending for or against the intervention.

In 2019, the American College of Rheumatology released guidelines for the management of osteoarthritis of the hand, hip, and knee. The guidelines do not mention pulsed electrical or electromagnetic stimulation, but they recommend against transcutaneous electrical stimulation for patients with knee and/or hip osteoarthritis. In 2021, the American College of Rheumatology released updated recommendations for the treatment of rheumatoid arthritis. All recommended treatments were pharmacologic. Use of electrical stimulation for treating 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

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 4/2019

Specialty Matched Consultant Advisory Panel review 2/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 4/2020

Specialty Matched Consultant Advisory Panel review 2/2021

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 4/2021

Specialty Matched Consultant Advisory Panel review 2/2022

Medical Director review 2/2022

Specialty Matched Consultant Advisory Panel review 2/2023

Medical Director review 2/2023

American Academy of Orthopaedic Surgeons. Management of osteoarthritis of the knee (non-arthroplasty). 2021; https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/oak3cpg.pdf.

Bagnato GL, Miceli G, Marino N, et al. Pulsed electromagnetic fields in knee osteoarthritis: a double blind, placebo-controlled, randomized clinical trial. Rheumatology (Oxford). Apr 2016; 55(4): 755-62. PMID 26705327

Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. Arthritis Care Res (Hoboken). Feb 2020; 72(2): 149-162. PMID 31908149

Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). Jul 2021; 73(7): 924-939. PMID 34101387

Specialty Matched Consultant Advisory Panel review 2/2024

Medical Director review 2/2024

Policy Implementation/Update Information

From policy entitled: Bionicare Stimulator

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)

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)
3/10/20	Reference added. Description section updated. Specialty Matched Consultant Advisory Panel review 2/19/2020. No change to policy statement. (eel)
3/23/21	Reference added. Description section updated. Specialty Matched Consultant Advisory Panel review 2/17/2021. No change to policy statement. (bb)
3/8/22	References updated. Description section updated. Specialty Matched Consultant Advisory Panel review 2/2022. Medical Director Review 2/2022. No change to policy statement. (tt)
3/7/23	References updated. Description section updated. Specialty Matched Consultant Advisory Panel review 2/2023. Medical Director Review 2/2023. No change to policy statement. (tt)
3/6/24	Description, regulatory status, policy guidelines, and references updated. No change to policy statement. Specialty Matched Consultant Advisory Panel review 2/2024. Medical Director Review 2/2024. (tt)