MEDICAL POLICY

POLICY TITLE	ELECTRICAL STIMULATION FOR THE TREATMENT OF ARTHRITIS AND MISCELLANEOUS CONDITIONS
POLICY NUMBER	MP-6.048

Effective Date:	10/1/2023

I. POLICY

Electrical or electromagnetic stimulation is considered **investigational** for the treatment of osteoarthritis, rheumatoid arthritis, or any other condition as there is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP 6.020 Transcutaneous Electrical Nerve Stimulation
MP 6.045 Sympathetic Therapy for the Treatment of Pain
MP 6.046 Threshold Electrical Stimulation as a Treatment of Motor Disorders
MP 6.047 Interferential Current Stimulation
MP 6.049 H-Wave Electrical Stimulation
MP 6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)
MP 6.051 Neuromuscular and Functional Neuromuscular Electrical Stimulation

II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND TOP

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 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 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. 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. 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 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 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 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.

With the exception of ActiPatch, nonprescription devices are not evaluated in this review.

IV. RATIONALE

TOP

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 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. More recent RCTs 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 that the technology results in an improvement in the net health outcome.

V. DEFINITIONS

TOP

510 (K) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

OSTEOARTHRITIS is a type of arthritis marked by progressive cartilage deterioration in the synovial joints and vertebrae.

RHEUMATOID ARTHRITIS is a chronic, inflammatory, destructive, and sometimes deforming collagen disease that has an autoimmune component. It is characterized by symmetric inflammation of synovial membranes and increased synovial exudate, leading to thickening of the membranes and swelling of the joints.

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

TOP

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical

policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

Procedure Codes							
E0762							

IX. REFERENCES

TOP

1. *Department of Health & Human Services. Correction to substantially equivalent letter of June 6, 2003 for BionicCare Stimulator. June 8, 2006. .* Accessed *March 28, 2022.*
2. *Yang X, He H, Ye W, et al. Effects of Pulsed Electromagnetic Field Therapy on Pain, Stiffness, Physical Function, and Quality of Life in Patients With Osteoarthritis: A Systematic Review and Meta-Analysis of Randomized Placebo-Controlled Trials. Phys Ther. Jul 19 2020; 100(7): 1118-1131. PMID 32251502*
3. *Negm A, Lorbergs A, Macintyre NJ. Efficacy of low frequency pulsed subsensory threshold electrical stimulation vs placebo on pain and physical function in people with knee osteoarthritis: systematic review with meta-analysis. Osteoarthritis Cartilage. Sep 2013; 21(9): 1281-9. PMID 23973142*
4. *Fary RE, Carroll GJ, Briffa TG, et al. The effectiveness of pulsed electrical stimulation in the management of osteoarthritis of the knee: results of a double-blind, randomized, placebo-controlled, repeated-measures trial. Arthritis Rheum. May 2011; 63(5): 1333-42. PMID 21312188*
5. *Li S, Yu B, Zhou D, et al. Electromagnetic fields for treating osteoarthritis. Cochrane Database Syst Rev. Dec 14 2013; (12): CD003523. PMID 24338431*
6. *Garland D, Holt P, Harrington JT, et al. A 3-month, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of a highly optimized, capacitively coupled, pulsed electrical stimulator in patients with osteoarthritis of the knee. Osteoarthritis Cartilage. Jun 2007; 15(6): 630-7. PMID 17303443*
7. *Zizic TM, Hoffman KC, Holt PA, et al. The treatment of osteoarthritis of the knee with pulsed electrical stimulation. J Rheumatol. Sep 1995; 22(9): 1757-61. PMID 8523357*
8. *Mont MA, Hungerford DS, Caldwell JR, et al. Pulsed electrical stimulation to defer TKA in patients with knee osteoarthritis. Orthopedics. Oct 2006; 29(10): 887-92. PMID 17061414*

9. *Farr J, Mont MA, Garland D, et al. Pulsed electrical stimulation in patients with osteoarthritis of the knee: follow up in 288 patients who had failed non-operative therapy. Surg Technol Int. 2006; 15: 227-33. PMID 17029181*
10. *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*
11. *Wuschech H, von Hehn U, Mikus E, et al. Effects of PEMF on patients with osteoarthritis: Results of a prospective, placebo-controlled, double-blind study. Bioelectromagnetics. Dec 2015; 36(8): 576-85. PMID 26562074*
12. *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. Aug 2013; 33(8): 2169-73. PMID 22451021*
13. *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. Jul 2011; 91(7): 1009-17. PMID 21642511*
14. *Dundar U, Asik G, Ulasli AM, et al. Assessment of pulsed electromagnetic field therapy with Serum YKL-40 and ultrasonography in patients with knee osteoarthritis. Int J Rheum Dis. Mar 2016; 19(3): 287-93. PMID 25955771*
15. *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. Aug 2010; 29(8): 927-31. PMID 20473540*
16. *de Paula Gomes CAF, Politti F, de Souza Bacelar Pereira C, et al. Exercise program combined with electrophysical modalities in subjects with knee osteoarthritis: a randomised, placebo-controlled clinical trial. BMC Musculoskelet Disord. Apr 20 2020; 21(1): 258. PMID 32312265*
17. *Bannuru RR, Osani MC, Vaysbrot EE, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. Osteoarthritis Cartilage. Nov 2019; 27(11): 1578-1589. PMID 31278997*
18. *American Academy of Orthopaedic Surgeons. Treatment of osteoarthritis of the knee. 2013;. Accessed March28, 2022.*
19. *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*
20. *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*
21. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 1.01.27, Electrical Stimulation for the Treatment of Arthritis. April 2023*

X. POLICY HISTORY

TOP

MP 6.048	**CAC 10/25/2011 Adopted BCBSA**. New Policy, information regarding BioniCare, BIO-1000 removed from MP- 6.020 Electrical Stimulation Modalitie and created in this separate policy. No change to policy statement,

	remains investigational
	CAC 10/30/12 Consensus review. References updated; no changes to policy statement. Codes reviewed 10/26/12
	CAC 11/26/13 Consensus review. No change to policy statements. References updated. Rationale section added. Changed FEP variation to reference the policy manual.
	CAC 11/25/14 Consensus review. No changes to the policy statements References and rationale updated. Background updated with new devices. Codes reviewed, no changes.
	CAC 11/24/15 Consensus review. Added reference to NHIC L28551 Transcutaneous Electrical Joint Stimulation Devices (TEJSD). Updated rationale and references. No change to policy statements. Coding updated.
	07/15/16 Administrative posting. LCD revised to reflect Noridian LCD 34821
	CAC 11/29/16 Consensus Review. No changes to the policy statements References and rationale updated. Coding reviewed. Variation reformatting.
	CAC 11/28/17 Consensus Review. No changes to the policy statements References and rationale updated. Coding reviewed.
	8/13/18 Minor revision. Electromagnetic stimulation added to the policy statement as investigational. Description/Background, Rationale, and Reference sections updated. Coding reviewed. Effective 3/1/19.
	5/20/19 Consensus review. No change to policy statements. References and summary of evidence reviewed.
	05/08/20 Consensus review. No change to policy statements. References and summary of evidence reviewed.
	4/29/21 Consensus review. No change to policy statement. References updated.
	12/10/21 Consensus review. No change to policy statement. References updated. Product Variations, Disclaimer, and Benefit Variations updated.
	3/28/2022 Consensus review. No changes to policy statement. References updates. No changes to coding.
	7/18/2023 Consensus review. No changes to policy statement. References updated. Coding reviewed, no changes.

Top