

EFFECTIVE DATE: 01|20|2015
POLICY LAST UPDATED: 08|21|2018

OVERVIEW

Pulsed electrical and electromagnetic stimulation are being investigated to improve functional status and relieve pain related to osteoarthritis (OA) and rheumatoid arthritis (RA) unresponsive to other standard therapies. 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 that are placed over the skin.

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare

Electrical stimulation for the treatment of arthritis is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Electrical stimulation for the treatment of arthritis is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

MEDICAL CRITERIA

Not applicable

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

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. 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.

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 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 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).

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.

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.

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.

For individuals who have arthritis who receive pulsed electrical or electromagnetic stimulation, the evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

There is no specific CPT code for electrical stimulation for the treatment of arthritis. HCPCS code E0762 may be used.

The following code is not covered for BlueCHIP for Medicare and not medically necessary for Commercial Products when filed with a diagnosis below.

E0762 Transcutaneous electrical joint stimulation device system, includes all accessories

ICD-10 diagnosis codes for which HCPCS code E0762 is not covered/not medically necessary.

M05.00-M05.9

M06.00-M06.9

M08.00-M08.99

M15.0-M19.93

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, November 2018

Provider Update, January 2017

Provider Update, April 2015
Provider Update, June 2014
Provider Update, August 2013

REFERENCES

1. Noridian Healthcare Solutions, LLC., Local Coverage Determination (LCD): Transcutaneous Electrical Joint Stimulation Devices (TEJSD) (L34821)
2. 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 metaanalysis. *Osteoarthritis Cartilage*. Sep 2013;21(9):1281-1289. PMID 23973142
3. 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):1333-1342. PMID 21312188
4. Li S, Yu B, Zhou D, et al. Electromagnetic fields for treating osteoarthritis. *Cochrane Database Syst Rev*. Dec 14 2013;12(12):CD003523. PMID 24338431
5. 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):630-637. PMID 17303443
6. 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):1757-1761. PMID 8523357
7. Mont MA, Hungerford DS, Caldwell JR, et al. Pulsed electrical stimulation to defer TKA in patients with knee osteoarthritis. *Orthopedics*. Oct 2006;29(10):887-892. PMID 17061414
8. 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*. Oct 2006;15:227-233. PMID 17029181
9. 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):755-762. PMID 26705327
10. 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):576-585. PMID 26562074
11. 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):2169-2173. PMID 22451021
12. 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):1009-1017. PMID 21642511
13. 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):287-293. PMID 25955771
14. 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):927-931. PMID 20473540
15. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis Cartilage*. Mar 2014;22(3):363-388. PMID 24462672
16. American Academy of Orthopaedic Surgeons. Treatment of osteoarthritis of the knee. 2013; <http://www.aaos.org/research/guidelines/guidelineoaknee.asp>. Accessed February 1, 2018.
17. 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 22563589
18. Singh JA, Saag KG, Bridges SL, Jr., et al. 2015 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. *Arthritis Rheumatol*. Jan 2016;68(1):1-26. PMID 26545940

[CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS](#)

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

