Medical Coverage Policy | Electrical Stimulation for Treatment of Arthritis

EFFECTIVE DATE: 01|20|2015
POLICY LAST UPDATED: 12|06|2016

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
Prior Authorization review is not required.

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
Electrical stimulation for the treatment of arthritis is considered **not medically necessary** as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

MEDICAL CRITERIA
Not applicable

BACKGROUND
Electrical stimulation is being investigated to improve functional status and 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 non-invasively 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. Combined magnetic fields deliver a time-varying field by superimposing the time-varying magnetic field onto an additional static magnetic field.

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 that are 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 volt 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 system 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. In 2009, the OrthoCor Knee System was cleared for marketing by FDA through the 510(k) process 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™.

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 radio frequency of 27.12 MHz. The device is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue. Palermo is another name for a device marketed by Ivivi Health Sciences.

A review of the literature has not found adequate evidence to indicate the use of pulsed electrical or electromagnetic stimulation for the treatment of arthritis will result in improvements in health outcomes. Therefore, electrical stimulation for the treatment of arthritis is considered not medically necessary as there is no proven efficacy.

COVERAGE

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

CODING

BlueCHiP for Medicare and Commercial Products

Although there is no code specific for electrical stimulation for the treatment of arthritis, E0762 is often used. E0762 is considered **not medically necessary**.

E0762

ICD-10 diagnosis codes for which CPT code E0762 is considered not medically necessary.

Electrical Stimulation
ICD 10 Dx Codes NMI

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, January 2017
Provider Update, April 2015
Provider Update, June 2014
Provider Update, August 2013

Provider Update, September 2012
Provider Update, August 2011
Provider Update, August 2010

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. 2013;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. 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
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):1757-1761. PMID 8523357
8. 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
9. 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
10. 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;15:227-233. PMID 17029181
11. 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
12. 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
13. 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
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):287-293. PMID 25955771
15. American Academy of Orthopaedic Surgeons. Treatment of osteoarthritis of the knee. 2013; http://www.aaos.org/research/guidelines/guidelineoaknee.asp. Accessed November 4, 2014.

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS