JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Medical Policy Manual** **Medical Policy**	*Policy Number*	CMS16.12
		Effective Date	11/01/2023
		Approval Date	08/15/2023
	Subject **Pulsed Electrical Stimulation Devices**	*Supersedes Date*	02/01/2023
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This document applies to the following Participating Organizations:

EHP	Johns Hopkins Advantage MD	Johns Hopkins Health Plan of Virginia Inc. (JHHPVA)	Priority Partners
US Family Health Plan			

Keywords: Pulsed Electrical Stimulation, Transcutaneous Electrical Joint Stimulation

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I. ACTION

	New Policy	
X	Revising Policy Number	CMS16.12
	Superseding Policy Number	
	Retiring Policy Number	

II. POLICY DISCLAIMER

Johns Hopkins Health Plans (JHHP) provides a full spectrum of health care products and services for Advantage MD, Employer Health Programs, Johns Hopkins Health Plan of Virginia Inc., Priority Partners, and US Family Health Plan. Each line of business possesses its own unique contract, benefits, regulations, and regulators' clinical guidelines that supersede the information outlined in this policy.

III. POLICY

For Advantage MD refer to: Medicare Coverage Database

- Local Coverage Determination (LCD) L34821 Transcutaneous Electrical Joint Stimulation Devices (TEJSD)

For Employer Health Program (EHP) refer to:

- Plan specific Summary Plan Descriptions (SPD's)

For Johns Hopkins Health Plan of Virginia Inc. (JHHPVA) refer to: Medicare Coverage Database (Effective 1/1/2024)

- Local Coverage Determination (LCD) L34821 Transcutaneous Electrical Joint Stimulation Devices (TEJSD)

For Priority Partners (PPMCO) refer to: Code of Maryland Regulations

- No specific information located in COMAR 10.67.01 – 10.67.13 (Accessed July24, 2023)

For US Family Health Plan (USFHP) refer to: Tricare Policy Manuals

- TRICARE Policy Manual 6010.63-M, April 1, 2021, Chapter 7, Section 18.2 Physical Medicine/Therapy

IV. POLICY CRITERIA

Unless specific benefits are provided under the member's contract, JHHP considers pulsed electrical stimulation (PES) devices, also known as transcutaneous electrical joint stimulation devices (TEJSD) (e.g., BioniCare® Knee System, JStim Joint System), experimental and investigational because they do not meet Technology Evaluation Criteria (TEC) as defined in CMS01.00 Medical Policy Introduction.

V. DEFINITIONS

Pulsed Electrical Stimulation (PES): PES is a non-invasive, low amplitude type of electrical stimulation proposed to aid in bone and cartilage repair in the treatment of osteoarthritis and rheumatoid arthritis. It is thought to stimulate the proliferation of chondrocytes and osteoblast function, which are mediated by electrical fields induced in the extracellular matrix by mechanical stresses. This type of electrical stimulation differs from traditional transcutaneous electrical nerve stimulation (TENS). The TENS deliver electrical pulses that temporarily block pain or reduce the perception of pain, where PES is proposed to repair the underlying cause of the pain (Hayes, 2011; VQ OrthoCare 2018).

Transcutaneous Electrical Joint Stimulation Devices (TEJSD): TEJSDs is a non-invasive modality designed to specifically target the joint tissue and cartilage by delivering low-amplitude pulsed electrical stimulation (PES) through topical electrodes and an external signal generator. The device delivers subsensory (below the sensory threshold) low level pulsed stimulation to the joint and is typically worn for at least six hours per day (Pain Management Technologies, 2023; VQ OrthoCare, 2018).

VI. BACKGROUND

Osteoarthritis (OA) is the most common chronic condition of the joints and can occur at any age, but is most common in middle-aged adults or older. According to the Arthritis foundation, one in two adults will develop symptoms of knee OA during their lives. The condition generally develops gradually and is characterized by the breakdown of cartilage that usually allows for smooth movement of the joint. As areas of the bone are no longer protected by cartilage, bone-on-bone rubbing occurs, causing damage to the bones. This is coupled with the inflammatory response generated as the body attempts to heal the damaged tissues, which can result in abnormal bone overgrowth and enlarged joints. This typically leads to pain, stiffness and decreased mobility. Non-surgical treatments include lifestyle changes to reduce obesity and increase activity level, physical therapy, bracing as well as pharmacologic treatment (NIH, 2022).

Despite appropriate conventional treatment, persistent symptoms of knee pain may occur and several alternative therapies, including pulse electrical stimulation, have been proposed. One such device is known as the BioniCare® Knee System. The Center for Medicare and Medicaid Services (CMS) describes this type of device as a transcutaneous electrical joint stimulation device (TEJSD) that delivers electrical stimulation intended to reduce the level of pain and symptoms associated with

arthritis in a joint. TEJSDs may have variation in the parameters of the current and how the current is applied. Pulse electrical stimulation is proposed to reduce pain, improve function and delay subsequent definitive surgery. According to manufacturer, VQ OrthoCare, the BioniCare® system delivers an imperceptible pulsed electrical signal that mimics the endogenous electric impulse that is diminished due to the physical changes in an osteroarthritic knee, and functions differently from transcutaneous electrical nerve stimulators (TENS) that block the body's pain signals. The device is currently marketed with an off-loading knee brace for use during the day, and an overnight wrap for sleeping. The electrical stimulation frequency is 100 Hz ± 5 Hz, the voltage range is from 00.0 to 12.0, and a monophasic spike-shaped pulse waveform is produced (CMS, 2017; VQ Orthocare, 2018).

Published evidence and clinical guidelines are inconclusive regarding the use of PES for treatment of osteoarthritis and rheumatoid arthritis. In 2011, Hayes reported that clinical studies showed mild-to-moderate improvement in OA symptoms, and assigned a C rating to this technology. The overall quality of the evidence was rated as low and it was noted that there is insufficient evidence to conclude that the BioniCare® Knee System alters long-term health outcomes. An update by Hayes in 2013 did not alter these findings. The American Academy of Orthopaedic Surgeons (AAOS) issued guidelines in 2013 on the treatment of OA of the knee. Regarding pulsed electrical stimulation, both the quality and strength of evidence were rated as low and Recommendation 3B states: "We are unable to recommend for or against the use of physical agents (including electrotherapeutic modalities) in patients with symptomatic osteoarthritis of the knee". The American College of Rheumatology (ACR), in collaboration with the Arthritis Foundation, published updated guidelines for management of OA in 2019. Strong recommendations were made for exercise, weight loss, bracing, NSAIDs, and intraarticular injections as an evidence-based approach for treatment of OA. Electrotherapeutic modalities were not listed as a recommendation for management of OA (AAOS, 2013; ACR, 2019; Hayes, 2013).

In 2011, Fary et al. conducted a randomized double-blinded, placebo- controlled trial to determine the effectiveness of subsensory, PES in the symptomatic management of OA of the knee. Analysis of the results concluded that "In this sample of subjects with mild-to-moderate symptoms and moderate-to-severe radiographic OA of the knee, 26 weeks of PES was no more effective than placebo." More recently, in 2015, Zeng et al. conducted a systematic review and network meta-analysis that examined multiple electrical stimulation therapies, inclusive of pulsed electrical stimulation. Results reported state this study did not find any advantage of PES in pain relief when compared with the control group. The evidence was limited due to the heterogeneity and small number of included trials as well as the limited sample size of some included studies (Fary et al., 2011; Zeng et al., 2015).

VII. CODING DISCLAIMER

Note: The following CPT/HCPCS codes are included below for informational purposes and may not be all inclusive. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member's specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee of payment. Other policies and coverage determination guidelines may apply.

Note: All inpatient admissions require preauthorization.

Adherence to the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits
Advantage MD: Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Employer Health Programs (EHP): Specific Summary Plan Descriptions (SPDs) supersedes JHHP Medical Policy. If there are no criteria in the SPD, apply the Medical Policy criteria.
Johns Hopkins Health Plan of Virginia Inc. (JHHPVA): Regulatory guidance supersedes JHHP Medical Policies. If there are no statutes, regulations, NCDs, LCDs, or LCAs, or other CMS guidelines, apply the Medical Policy criteria.
Priority Partners (PPMCO): Regulatory guidance supersedes JHHP Medical Policy. If there are no criteria in COMAR regulations, or other State guidelines, apply the Medical Policy criteria.
US Family Health Plan (USFHP): Regulatory guidance supersedes JHHP Medical Policy. If there are no TRICARE policies, or other regulatory guidelines, apply the Medical Policy criteria.

VIII. CODING INFORMATION

HCPCS CODE	DESCRIPTION
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories

IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins Health Plans (JHHP) Medical Policy Team during the development and implementation of this medical policy. The Medical Policy Team will continue to monitor and review any newly published clinical evidence and revise the policy and adjust the references below accordingly if deemed necessary.

X. REFERENCES

Aetna. (2023 May 9). *Electrical Stimulation for Pain.* Medical Clinical Policy Bulletins. Number: 0011.http://www.aetna.com

American Academy of Orthopaedic Surgeons (AAOS). (2013). *Treatment of Osteoarthritis of the Knee - 2nd Edition.* Evidence-Based Clinical Practice Guideline. https://www.aaos.org

Kolasinski, S. L., Neogi, T., Hochberg, M. C., Oatis, C., Guyatt, G., Block, J., Callahan, L., Copenhaver, C., Dodge, C., Felson, D., Gellar, K., Harvey, W. F., Hawker, G., Herzig, E., Kwoh, C. K., Nelson, A. E., Samuels, J., Scanzello, C., White, D., Wise, B., Reston, J. (2020). 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. *Arthritis & rheumatology (Hoboken, N.J.), 72*(2), 220–233. https://doi.org/10.1002/acr.24131

Arthritis Foundation. (2018). *Osteoarthritis.* https://www.arthritis.org

BlueCross BlueShield of North Carolina. (2023, February). *Electrical Stimulation for the Treatment of Arthritis.* Corporate Medical Policy. https://www.bluecrossnc.com

Cigna. (2023 September 15). Electrical Stimulation Therapy and Devices*in a Home Setting*. Medical Coverage Policy Number: 0160. https://static.cigna.com

Deveza, L. A. & Bennell K. (2023). Management of knee osteoarthritis. *UpToDate*. Retrieved July 23, 2023 from: https://www.uptodate.com

Deveza, L.A. & Bennell, K. (2023). Management of moderate to severe knee osteoarthritis. *UpToDate*. Retrieved July 23, 2023 from: https://www-uptodate-com.

Fary, R. E., Carroll, G. J., Briffa, T. G., & Briffa, N. K. (2011). 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 & Rheumatology*, *63*(5), 1333-1342. https://doi.org/10.1002/art.30258

Hayes, Inc., (2013). BioniCare® Knee System (VQ Ortho Care) for Treatment of Osteoarthritis of the Knee. Health Technology Assessment. [Archived November 17, 2014]. from: https://www.hayesinc.com

Hochberg, M.C., Altman, R.D., April, K. T., Benkhalti, M., Guyatt, G., McGowan, J., Towheed, T., Welch, V., Wells, G., Tugwell, P., & American College of Rheumatology. (2012). American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis care & research*, *64*(4), 465-467. DOI: 10.1002/acr.21596

Humana. (2023, April 27) E*lectrical Stimulators for Pain and Nausea/Vomiting.* Medical Coverage Policy Number: HUM-0412-031. http://apps.humana.com

National Institute of Health. (2022). Osteoarthritis. *MedlinePlus.*: https://ghr.nlm.nih.gov/

Negm, A., Lorberg, A., & Macintyre, N.J. (2013). 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 and cartilage*, *21*(9), 1281-1289. DOI: 10.1016/j.joca.2013.06.015

Novak, S., Guerron, G., Zou, Z., Cheung, G., & Berteau, J. P. (2020). New Guidelines for Electrical Stimulation Parameters in Adult Patients With Knee Osteoarthritis Based on a Systematic Review of the Current Literature. *American journal of physical medicine & rehabilitation*, *99*(8), 682–688. doi: 10.1097/PHM.0000000000001409

Pain Management Technologies. (2023). *JStim Joint System*. http://paintechnology.com

Pelland, L., Brosseau, L., Casimiro, L., Welch, V., Tugwell, P., & Wells, G. (2002). Electrical stimulation for the treatment of rheumatoid arthritis. The Cochrane Database of Systematic Reviews, (2), CD003687. https://doi.org/10.1002/14651858.cd003687

Rice, D., McNair, P., Huysmans, E., Letzen, J., & Finan, P. (2019). Best Evidence Rehabilitation for Chronic Pain Part 5: Osteoarthritis. *Journal of Clinical Medicine*, *8*(11), 1769 https://doi.org/10.3390/jcm8111769

Rutjes A. W., Nüesch, E., Sterchi, R., Kalichman, L., Hendriks, E., Osiri, M., Brosseau, L., Reichenbach, S., & Jüni, P. (2009). Transcutaneous electrostimulation for osteoarthritis of the knee. *The Cochrane database of systematic reviews*, *2009*(4), CD002823. DOI: 10.1002/14651858.CD002823.pub2

United Healthcare. (2023, June 1). *Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation.* Medical Policy Number: CS036. https://www.uhcprovider.com

VQ OrthoCare. (2022). *BioniCare® Knee System.* https://www.vqorthocare.com

VQ OrthoCare. (2018). *What is BioniCare?* https://bionicare.com

Zeng, C., Li, H., Yang, Z., Deng, H., Yang, Y., Zhang, Y., & Lei, G.H. (2015). Electrical stimulation for pain relief in knee osteoarthritis: systematic review and network meta-analysis. *Osteoarthritis and Cartilage, 23*(2), 189-202. https://doi.org/10.1016/j.joca.2014.11.014

Zizic, T. M., Hoffman, K. C., Holt, P.A., Hungerford, D. S., O'Dell, J. R., Jacobs, M. A., Lewis, C. G., Deal, C. L., Caldwell, J. R., & Cholewczynski, J. G. (1995). The treatment of osteoarthritis of the knee with pulsed electrical stimulation. *The Journal of rheumatology, 22*(9), 1757-1761.

XI. APPROVALS

Historical Effective Dates: 06/2003, 10/21/2005, 10/13/2006, 03/03/2008, 03/02/2009, 06/04/2010, 08/23/2011, 03/07/2014, 04/01/2019, 02/19/2019, 11/01/2021, 02/01/2023, 11/01/2023