This document applies to the following Participating Organizations:

| EHP     | Johns Hopkins Advantage MD | Priority Partners | US Family Health Plan |

Keywords: Pulsed Electrical 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 HealthCare LLC (JHHC) provides a full spectrum of health care products and services for Employer Health Programs, Priority Partners, Advantage MD and US Family Health Plan. Each line of business possesses its own unique contract and guidelines which, for benefit and payment purposes, should be consulted to know what benefits are available for reimbursement.

Specific contract benefits, guidelines or policies supersede the information outlined in this policy.

### III. POLICY

For Advantage MD:

Refer to Local Coverage Determination (LCD) L34821 Transcutaneous Electrical Joint Stimulation Devices (TEJSD), [https://www.cms.gov](https://www.cms.gov)

Medicare does not have a National Coverage Determination (NCD) for Pulse Electrical Stimulation for the Knee.

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IV. POLICY CRITERIA

A. Unless specific benefits are provided under the member’s contract, JHHC considers pulsed electrical stimulation (as with the BioniCare® Knee Device) unproven, since there is insufficient evidence to conclude that this treatment provides any significant benefit to the patients with osteoarthritis of the knee. This modality does not meet Technology Evaluation Criteria (TEC).

V. DEFINITIONS

Pulsed Electrical Stimulation (PES): A type of electrical stimulation proposed to aid in bone and cartilage repair. 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 (Hayes, 2011).

Transcutaneous Electrical Joint Stimulation Device: A modality delivering low-amplitude pulsed electrical stimulation non-invasively through topical electrodes and an external signal generator. The device delivers electrical impulses of 0.0 to 12.0 volt output to the joint and is typically worn for at least six hours per day.

VI. BACKGROUND

Osteoarthritis (OA) is the most common chronic condition of the joints and can occur at any age, but is most common in adults middle-aged 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 causes 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 (NIH, 2019). Non-surgical treatments include lifestyle changes to reduce obesity and increase activity level, physical therapy, bracing as well as pharmacologic treatment.

Despite appropriate conventional treatment, persistent symptoms of knee pain may occur and several alternative therapies including electrical stimulation have been proposed. One such noninvasive pulse electrical stimulation (PES) device is known as the BioniCare Knee Device formerly, (the BioniCare® Bio-1000 System). The Center for Medicare and Medicaid Services (CMS, 2017) describes this devise 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. TEJSD's 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 VQ Orthocare (2019), 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 osteoarthritic 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 day use, 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.

Published evidence and clinical guidelines are inconclusive. In 2011 Hayes reported that clinical studies showed mild-to-moderate improvement in OA symptoms, and assigned a C rating. 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 osteoarthritis of the knee. Regarding pulsed electrical stimulation, both the evidence 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". In 2011 Fary conducted a randomized double-blind, placebo-controlled trial to determine the effectiveness of subsensory, pulsed electrical stimulation (PES) in the symptomatic management of osteoarthritis (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 (Zeng). The Medicare Local Coverage Decision issued for Maryland states: "There is insufficient published clinical evidence to establish that treatment with TEJSD [transcutaneous electrical joint stimulation] meets the requirements to be considered reasonable and necessary for the treatment of osteoarthritis or any other condition".

VII. CODING DISCLAIMER

CPT Copyright 2018 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member’s specific benefit plan determines coverage and referral requirements. All inpatient admissions require preauthorization.

| Compliance with the provision in this policy may be monitored and addressed through post payment data analysis and/or medical review audits |
|-----------------------------------------------|-----------------------------------------------|
| Employer Health Programs (EHP) refer to specific Summary Plan Description (SPD). If there is no criteria in the SPD, apply the Medical Policy criteria. | Priority Partners (PPMCO) refer to COMAR guidelines and PPMCO SPD then apply the Medical Policy criteria. |
| US Family Health Plan (USFHP), TRICARE Medical Policy supersedes JHHC Medical Policy. If there is no Policy in TRICARE, apply the Medical Policy Criteria. | Advantage MD, LCD and NCD Medical Policy supersedes JHHC Medical Policy. If there is no LCD or NCD, apply the Medical Policy Criteria. |

VIII. CODING INFORMATION

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<tr>
<th>HCPCS CODE</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>E0762</td>
<td>Transcutaneous electrical joint stimulation device system, includes all accessories</td>
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<tr>
<th>ICD10 CODES</th>
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<tr>
<td>M17.0 - M17.9</td>
<td>Osteoarthritis of knee</td>
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IX. REFERENCE STATEMENT

Analyses of the scientific and clinical references cited below were conducted and utilized by the Johns Hopkins HealthCare LLC (JHHC) Medical Policy Team during the development and implementation of this medical policy. Per NCQA standards, the Medical Policy Team will continue to monitor and review any newly published clinical evidence and adjust the references below accordingly if deemed necessary.

X. REFERENCES


COMAR Regulations, 10.46.06.03. Competency Requirements for Physical Agent Modalities, Definitions. Retrieved from http://www.dsd.state.md.us


Subject
Pulse Electrical Stimulation for the Knee


XI. APPROVALS