

Policy: MP149

Section: Medical Benefit Policy

Subject: Pulsed Electrical Stimulation for the Treatment of Osteoarthritis

Applicable Lines of Business

| | | | |
|------------|---|------|---|
| Commercial | X | CHIP | X |
| Medicare | X | ACA | X |
| Medicaid | X | | |

I. Policy: Pulsed Electrical Stimulation for the Treatment of Osteoarthritis

II. Purpose/Objective:

To provide a policy of coverage regarding Pulsed Electrical Stimulation for the Treatment of Osteoarthritis

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or

management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

DESCRIPTION:

Pulsed electrical stimulation has been proposed as a treatment for symptomatic relief in osteoarthritis. Several devices have been marketed including, but not limited to the BionCare® BIO-1000™ system, OrthoCor™ Active Knee System, SofPulse™, ActiPatch®, Magnetofield®.

EXCLUSIONS:

The Plan does **NOT** provide coverage for the use of pulsed electrical stimulation for the treatment of osteoarthritis because it is considered **experimental, investigational or unproven**. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Pulsed electrical stimulation for treatment of osteoarthritis

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

E1399 Durable Medical Equipment, miscellaneous
E0762 Transcutaneous electrical joint stimulation device

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL.

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Geisinger Technology Assessment Committee Triage Group. Pulsed Electrical Stimulation for OA of the Knee. Nov. 18, 2004.

Hulme J, Robinson V, DeBie R, Wells G, Judd M, Tugwell P. Electromagnetic fields for the treatment of osteoarthritis. The Cochrane Database of Systematic Reviews. Vol 2, 2004.

Zizic TM, Hoffman KC, Holt PA, et. al. The treatment of osteoarthritis of the knee with pulsed electrical stimulation. J Rheumatol 1995;22:1757-1761.

Lippiello L, Chakkalakal D, Connolly JF. Pulsing direct current-induced repair of articular cartilage in rabbit osteochondral defects. J Ortho Research 1990(8(2)). <http://www.bionicare.com>

Zizic TM, Hoffman KC, He YD, et. al. The treatment of rheumatoid arthritis of the hand with pulsed electrical fields. Electricity and Magnetism in Biology and Medicine 1999. <http://www.bionicare.com>

Caldwell JR. Pulsed electrical stimulation in the treatment of rheumatoid arthritis. *Arthritis Rheum* 1994:S338.
<http://www.bionicare.com>

Mont MA, Hungerford DS, Caldwell JR, et.al. The use of pulsed electrical stimulation to defer total knee arthroplasty in patients with osteoarthritis of the knee. Poster Presentation. American Academy of Orthopedic Medicine 2004.

Mont MA, Jones LC, Hungerford DS, et. al. Treatment of osteoarthritis of the knee with Bionicare electrotherapy. Poster Presentation. American Academy of Orthopaedic Surgeons 1999

Trock DH, Bollet AJ, Dyer RH, et, al. A double blind trial of the clinical effects of pulsed electromagnetic fields in osteoarthritis. *J Rheum.*1993 mar;20(3):456-460.

Mont MA, Hungerford DS, Caldwell JR, Hoffman KC, He YD, Jones LC, Zizie TM. The Use of Pulsed Electrical Stimulation (PES) to Defer Total Knee Arthroplasty (TKA) in Patients with Osteoarthritis (OA) of the Knee. Poster Presentation. American Academy of Orthopedic Medicine 2004.

Winifred S. Hayes. Health Technology Brief- BioniCare Bio-1000 System for Osteoarthritis of the Knee. April 21,2005.

ECRI. HTAIS Hotline Response. Pulsed Electrical Stimulation (PES) for Osteoarthritis of the Knee. August 25, 2005. (Updated 5/19/11)

ECRI Institute, Target database. Transcutaneous electrical joint stimulation for knee osteoarthritis. Jan. 2006.

Farr, J, Mont, MA, Garland, D, Caldwell, JR, and Zizic, TM. 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.

Garland, D, Holt, P, Harrington, JT, Caldwell, J, Zizic, T, and Cholewczynski, J. 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.* 2007;15(6):630-637

Rutjes, AW, Nuesch, E, Sterchi, R, Kalichman, et al. Transcutaneous electrostimulation for osteoarthritis of the knee. *Cochrane Database Syst Rev.* 2009;(4):CD002823.

Langworthy, MJ, Saad, A, and Langworthy, NM. Conservative treatment modalities and outcomes for osteoarthritis: the concomitant pyramid of treatment. *Phys Sportsmed.* 2010;38(2):133-145.

Fary, RE, Carroll, GJ, Briffa, TG, and Briffa, NK. 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.* 2011;63(5):1333-1342.

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* 2011; 63(5):1333-42.

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* 2011; 91(7):1009-17.

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):1281-1289.

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.

Bagnato GL, Miceli G, Marino N, et al. Pulsed electromagnetic fields in knee osteoarthritis: a double blind, placebo-controlled, randomized clinical trial. *Rheumatology Apr* 2016;55(4):755-762

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.* 2020; 21(1): 258.

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.

Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis care & research.* 2021;73(7):924-39.

Tong J, Chen Z, Sun G, et al. The Efficacy of Pulsed Electromagnetic Fields on Pain, Stiffness, and Physical Function in Osteoarthritis: A Systematic Review and Meta-Analysis. *Pain Res Manag.* 2022;2022:993989

This policy will be revised as necessary and reviewed no less than annually.

Devised: 12/10/04

Revised: 12/05 (updated references); 12/06 (coding); 12/19 (added examples)

Reviewed: 12/07, 12/08, 01/10, 1/11, 1/12, 1/13, 1/14, 1/15, 1/16; 1/17, 12/17, 12/18, 12/20, 12/21, 12/22, 12/23

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.