Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP066

Section: Medical Benefit Policy

Subject: Extracorporeal Shock Wave Treatment for Musculoskeletal Indications

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

I. Policy: Extracorporeal Shock Wave Treatment for Musculoskeletal Indications

II. Purpose/Objective:
To provide a policy of coverage regarding Extracorporeal Shock Wave Treatment for Musculoskeletal Indications

III. Responsibility:

A. Medical Directors

B. Medical Management Department

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
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:
Extracorporeal shock wave treatment [aka, Extracorporeal Pulse Activation Technology (EPAT)] is a non-invasive procedure that uses the force of an acoustic shock wave. Although there is support in the medical literature for the efficacy of this treatment for plantar fasciitis, the healing mechanism of extracorporeal shock wave treatment of this condition has not been described.

INDICATIONS:
Skeletally mature members diagnosed with chronic plantar fasciitis of six (6) months duration or more that has been refractory to three (3) conservative treatment options such as rest, anti-inflammatory medications, physical therapy, corticosteroid injections and/or heel orthotics.

LIMITATIONS:
There is inadequate evidence in the published, peer-reviewed medical literature to establish the safety and/or efficacy of Extracorporeal shock wave treatment in the following groups:

- Members on anticoagulation therapy
- Children
- Pregnant women
- Paget's disease
- History of bleeding disorder
- Diabetic neuropathy
- Severe osteoarthritis
- Rheumatoid arthritis
- Malignancy
- Significant peripheral vascular disease
- Osteomyelitis
- Tarsal tunnel syndrome
- Fracture of the foot or ankle

Coverage will be limited to ESWT using the high energy, single treatment protocol approved by the FDA. If repeat treatment is requested, services will be limited to a total of 2 treatments per foot per occurrence. There is insufficient evidence in the published, peer-reviewed medical literature to support the efficacy of this treatment beyond 2 treatment sessions.

EXCLUSIONS:
There is insufficient evidence in the published peer- reviewed medical literature to support ESWT using FDA approved low energy, multiple treatment protocols. The treatment is considered **experimental, investigational or unproven** and is **NOT COVERED.** 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.

The Plan does **NOT** provide coverage for ESWT as a treatment for any musculoskeletal indication other than plantar fasciitis, including but not limited to tendonitis of the shoulder, tendonitis of the elbow, non-union fractures or avascular necrosis of the hip 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.

There is insufficient evidence in the published peer- reviewed medical literature to support ESWT for indications such as, but not limited to, Peyronie's disease, erectile dysfunction, angina pectoris, breast cancer-related lymphedema, and wound healing. 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. Use of ESWT for the treatment of these conditions is considered **experimental, investigational or unproven** and is **NOT COVERED**.

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: Extracorporeal Shock Wave Treatment
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.***

0101T Extracorporeal shock wave involving musculoskeletal system, not otherwise specified,
0102T Extracorporeal shock wave, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle
0512T Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care, initial wound
0513T Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care, each additional wound (list separately in addition to code for primary procedure)
28890 Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia

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 supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:
Thiel M, "Application of Shock Waves in Medicine", *Clinical Orthopaedics and Related Research*, 387:18-21, 2001.

Wild C, Mahmoud K, Wanke S, "Extracorporeal Shock Wave Therapy in Orthopedics", *International Journal of Technology Assessment in Health Care*, 16(1):199-209, 2000.

Extracorporeal Shock Wave Treatment for Musculoskeletal Indications, TEC Evaluation, 16(20):1-23, April 2002.

Rompe JD, Schoellner C, Naff B, "Evaluation of Low-Energy Extracorporeal Shock Wave Application for Treatment of Chronic Plantar Fasciitis", *Journal of Bone and Joint Surgery*, 84A(3):335-341, Mar 2002.

Weil LS, Roukis TS, Weil LS, Borrelli AH, "Extracorporeal Shock Wave Therapy for the Treatment of Chronic Plantar Fasciitis: Indications, Protocol, Intermediate Results, and a Comparison to Results of Fasciotomy", *Journal of Foot & Ankle Surgery*, 41(3):166-172, 2002.

Wang CJ, Chen HS, Huang TW," Shockwave Therapy for Patients with Plantar Fasciitis: A One-Year Follow-up Study", *Foot & Ankle International*, 23(3)204-207, Mar. 2002.

Alvarez R, "Preliminary Results on the Safety and Efficiacy of the Ossatron® for Treatment of Plantar Fasciitis", *Foot & Ankle International*, 23(3), Mar. 2002

Extracorporeal Shock Wave Treatment (Lithotripsy) for Plantar Fasciitis, Geisinger Technology Assessment Committee, July 10, 2002

Ogden JA, Toth-Kischkat A, Schulteiss R, "Principals of Shock Wave Therapy", *Clinical Orthopaedics and Related Research*, 387:8-17, 2001

Ogden JA, Alvarez RG, Levitt R, Marlow M, "Shock Wave Therapy (Orthotripsy®) in Musculoskeletal Disorders", *Clinical Orthopaedics and Related Research*, 387:22-40, 2001.

Ogden JA, Alvarez R, Levitt R, Cross GL, Marlow M, "Shock Wave Therapy for Chronic Proximal Plantar Fasciitis", Clinical Orthopaedics and Related research, 387:47-59, 2001

Buchbinder R, Ptasznik R, et. al. "Ultrasound-Guided Extracorporeal Shock Wave Therapy for Plantar Fasciitis – A Randomized Controlled Trial", JAMA. 288(11):1364-1372, Sept. 18, 2002.

Weil LS, Roukis TS, Weil LS, Borelli AH., "Extracorporeal Shock Wave Therapy for the Treatment of Chronic Plantar Fasciitis: Indications, Protocol, Intermediate Results, and a Comparison of Results to fasciotomy", Journal of Foot and Ankle Surgery", 41(3):166-172, May-June 2002.

Strash WW, Perez RR, " Extracorporeal Shockwave Therapy for Chronic Proximal Plantar Fasciitis", Clinics in Podiatric Medicine and Surgery. 19(4):467-476, 2002.

Alvarez RG, Ogden JA, Jaakkola J, Cross L, " Symptom duration of plantar fasciitis and the effectiveness of orthotripsy", Foot & Ankle International 24(12):916-921.Dec. 2003.

Ogden JA, Alvarez RG, Levitt RL, Johnson JE, Marlow ME. Electrohydraulic high energy shock wave treatment for chronic plantar fasciitis. Journal of Bone and Joint Surgery. Oct 2004 86A(10): 2216-2226.

Furia JP. The safety and efficacy of high energy extracorporeal shock wave therapy in active, moderately active, and sedentary patients. Orthopedics 2005; 28:685 Ortho Supersite
http://www.orthosupersite.com/default.asp?page=view&rid=3586

Wang CJ, Wang FS, Yang KD, Weng LH, Ko JY. Long-term Results of Extracorporeal Shockwave Treatment for Plantar Fasciitis. Am J Sports Med 2006;34 592-596

Geisinger Technology Assessment Committee Triage. Low-Level Extracorporeal Shock Wave Therapy for Plantar Fasciitis. July 30, 2008.

Blue Cross Blue Shield Association, Technology Evaluation Center. Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis. Technology assessment. 2005 Mar.

California Technology Assessment Forum. Extracorporeal shock wave therapy (ESWT) for plantar fasciitis not responding to conservative therapy. June 20, 2007.

Chow IH, Cheing GL. Comparison of different energy densities of extracorporeal shock wave therapy (ESWT) for the management of chronic heel pain. Clin Rehabil. 2007 Feb;21(2):131-41.

ECRI Institute. Extracorporeal shockwave therapy for the treatment of plantar fasciitis [Windows on Medical Technology]1. 2006.

ECRI Institute. Extracorporeal shockwave therapy for epicondylitis [Hotline]. Current as of 8/17/07.

Haake M, Buch M, Shoellner C, Goebel F, Vogel M, Mueller I, et al. Extracorporeal shock wave therapy for plantar fasciitis: randomised controlled multicentre trial. BMJ. 2003 Jul 12;327(7406):75.

HAYES Medical Technology Directory™. Extracorporeal Shock Wave Therapy for Chronic Plantar Fasciitis. Lansdale, PA: HAYES Inc.; ©2005 Winifred S. Hayes, Inc. Originally published 2001 Apr. Last updated February 13, 2008.

Institute for Clinical Systems Improvement (ICSI), Technology Assessment Committee. Extracorporeal Shock Wave Therapy for Plantar Fasciitis. November, 2004. Accessed June 2008. Available at URL address:
http://www.icsi.org/knowledge/detail.asp?catID=107&itemID=1926

Liang, HW, Wang, TG, Chen, WS, and Hou, SM. Thinner Plantar Fascia Predicts Decreased Pain After Extracorporeal Shock Wave Therapy. *Clin Orthop Relat Res*. 2007 Mar 9;460:219-25.

Moretti, B, Garofalo, R, Patella, V, Sisti, GL, Corrado, M, and Mouhsine, E. Extracorporeal shock wave therapy in runners with a symptomatic heel spur. *Knee Surg Sports Traumatol Arthrosc*. 2006;14(10):1029-1032.

Rompe JD, Meurer A, Nafe B, Hofmann A, Gerdesmeyer L. Repetitive low-energy shock wave application without local anesthesia is more efficient than repetitive low-energy shock wave application with local anesthesia in treatment of chronic plantar fasciitis. J Orthop Res. 2005;23:931-41.

Speed CA, Nichols D, Wies J, Humphreys H, Richards C, Burnet S, et al. Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomised controlled trial. J Orthop Res. 2003 Sep;21(5):937-40.

Roles, NC Maudsley RH. Radial tunnel syndrome: resistant tennis elbow as a nerve entrapment. J Bone Joint Surg Br. 1972;54:499-508.

U.S. Food and Drug Administration (FDA). Premarket approvals. Updated 2001 Mar 7. Accessed

Nov 5, 2004. Available at URL address:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm

Gerdesmeyer L, Frey C, Vester J, Maier M, Weil Jr. L, Weil Sr. L, Russlies M, Stinstra J, Scurran B, Fedder K, Diehl P, lohrer H, Henne M and Gollwitzer H. Radial extracorporeal shock wave therapy is safe and effective in the treatment of chronic recalcitrant plantar fasciitis. Am J Sports Med 2008.

Hausdorf J, Lemmens MAM, Heck KDW, et al. Selective loss of unmyelinated nerve fibers after extracorporeal shockwave application to the musculoskeletal system. Neuroscience 2008;155:138-144.

Hausdorf J, Lemmens MAM, Kaplan S, et al. Extracorporeal shockwave application to the distal femur of rabbits diminishes the number of neurons immunoreactive for substance P in dorsal root ganglia L5. Brain Research 2008:96-101.

Metzner G, Dohnalek C, Aigner E. High-energy Extracorporeal Shock-Wave Therapy (ESWT) for the treatment of chronic plantar fasciitis. Foot Ankle Int. 2010 Sep;31(9):790-6.

Fojecki GL, Tiessen S, Osther PJ. Extracorporeal shock wave therapy (ESWT) in urology: A systematic review of outcome in Peyronie's disease, erectile dysfunction and chronic pelvic pain. World J Urol. 2016 Apr 23

Cebicci MA, Sutbeyaz ST, Goksu SS, et al. Extracorporeal shock wave therapy for breast cancer-related lymphedema: A pilot study. Arch Phys Med Rehabil. 2016 Mar 15

Slikkerveer J, de Boer K, Robbers LF, et al. Evaluation of extracorporeal shock wave therapy for refractory angina pectoris with quantitative analysis using cardiac magnetic resonance imaging: A short communication. Neth Heart J. 2016;24(5):319-325.

Vardi Y, Appel B, Kilchevsky A, Gruenwald I. Does low intensity extracorporeal shock wave therapy have a physiological effect on erectile function? Short-term results of a randomized, double-blind, sham controlled study. J Urol. 2012;187(5):1769-1775.

Sun, J, Gao, F, Wang, Y, Sun, W, Jiang, B, Li, Z. Extracorporeal shock wave therapy is effective in treating chronic plantar fasciitis: A meta-analysis of RCTs. Medicine. April, 2017.

Wu, K.T.; Chou, W.Y.; Wang, C.J.; Chen, C.Y.; Ko, J.Y.; Chen, P.C.; Cheng, J.H.; Yang, Y.J. Efficacy of Extracorporeal Shockwave Therapy on Calcified and Noncalcified Shoulder Tendinosis: A Propensity Score Matched Analysis.Biomed. Res. Int. 2019, 2019, 2958251.

Stania M, Juras G, Chmielewska D, et al. Extracorporal Shock Wave Thrapy for Achilles Tendinopathy. Biomed Res Int. Published online 2019 Dec 26

Testa G, Vescio A, Perez S, Consoli A, et al. Extracorporeal Shockwave Therapy Treatment in Upper Limb Diseases: A Systematic Review. J Clin Med. 2020 Feb 6;9(2). pii: E453.

ECRI Institute. Extracorporeal Shock Wave Therapy for Chronic Lateral Hip Pain. November 2020

Yoon SY, Kim YW, Shin IS, et al. Does the type of extracorporeal shock therapy influence treatment effectiveness in lateral epicondylitis? A systematic review and meta-analysis. Clin Orthop Relat Res. 2020 Oct;478(10):2324-2339

Ramon, S, Russo, S, Santoboni, F, et al. Focused shockwave treatment for greater trochanteric pain syndrome: a multicenter, randomized, controlled clinical trial. J Bone Joint Surg Am. 2020;102(15):1305-1311

Gazendam A, Ekhtiari S, Axelrod D, et al. Comparative efficacy of nonoperative treatments for greater trochanteric pain syndrome: A systematic review and network meta-analysis of randomized controlled trials. Clin J Sport Med. 2021

Mansur NSB, Matsunaga FT, Carrazzone OL, et al. Shockwave therapy plus eccentric exercises versus isolated eccentric exercises for Achilles insertional tendinopathy: A double-blinded randomized clinical trial. J Bone Joint Surg Am. 2021 May 24

Aldajah S, Alashram AR, Annino G, et al. Analgesic Effect of Extracorporeal Shock-Wave Therapy in Individuals with Lateral Epicondylitis: A Randomized Controlled Trial. J Funct Morphol Kinesiol. Mar 18 2022; 7(1)

Sansone V, Ravier D, Pascale V, et al. Extracorporeal Shockwave Therapy in the Treatment of Nonunion in Long Bones: A Systematic Review and Meta-Analysis. J Clin Med. Apr 01 2022; 11(7).

Shao H, Zhang S, Chen J, et al. Radial extracorporeal shockwave therapy reduces pain and promotes proximal tendon healing after rotator cuff repair: Randomized clinical trial. Ann Phys Rehabil Med. 2023 Apr 5;66(4):101730.

ElGendy MH, Mazen MM, Saied AM, et al. Extracorporeal Shock Wave Therapy vs. Corticosteroid Local Injection in Shoulder Impingement Syndrome : A Three-Arm Randomized Controlled Trial. Am J Phys Med Rehabil. Jun 01 2023; 102(6): 533-540

Stania M, Juras G, Marszałek W, et al. Analysis of pain intensity and postural control for assessing the efficacy of shock wave therapy and sonotherapy in Achilles tendinopathy - A randomized controlled trial. Clin Biomech Jan 2023; 101: 105830.

Rai S, Rajauria S, Khandelwal N, et al. Intralesional Steroid Injection Versus Extracorporeal Shockwave Therapy in the Treatment of Plantar Fasciitis: A Comparative, Prospective, Case Series Study. Cureus. Jan 2023; 15(1): e33593.

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

Devised: 7/02

Revised: 7/03 (add limitations); 7/04; 7/05 (reference); 8/09, 3/16 (removed P/A); 2/17 (added exclusions)

Reviewed: 7/07, 7/08, 10/10, 10/11, 10/12, 10/13, 10/14, 10/15, 2/18, 2/19, 2/20, 2/21, 2/22, 2/23, 2/24

CMS UM Oversight Committee Approval: 12/23, 5/24