MEDICAL POLICY

Medical Policy Title	**Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds**
Policy Number	**2.01.31**
Current Effective Date	March 20, 2025
Next Review Date	March 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Extracorporeal shock wave therapy (ESWT) for the treatment of musculoskeletal conditions, including, but not limited to, chronic plantar fasciitis, tendinitis of the shoulder and elbow, and non-union of fractures is considered **investigational**.

II. ESWT as a treatment for wound-healing is considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

ESWT is a noninvasive treatment that uses shock waves or sound waves to treat pain and, to promote healing of musculoskeletal and soft tissue injuries. ESWT is also known as orthotripsy and was initially developed as kidney stones treatment and has expanded into orthopedic and rehabilitation therapies. ESWT uses externally applied shock waves that are directed outside the body onto the area to be treated (e.g., the heel area for plantar fasciitis and the elbow area for tendinitis). The mechanism by which EWST might have an effect on musculoskeletal condition is not well defined.

ESWT may disrupt fibrous tissue, allowing for the subsequent promotion of revascularization and healing of tissue. It is believed that the direct and indirect effects of the shock waves may damage cell membranes, so that nociceptors cannot build up a potential to transmit pain signals. Chronic conditions such as tendinitis can be associated with a substantial degree of scarring and calcium deposit. Calcific deposits may restrict motion, encroach on nerves and blood vessels, causing pain and dysfunction. It is thought that the shock waves will break up these deposits, loosen structures, and promote resorption of calcium, thereby decreasing pain and improving function.

There are two types of ESWT, focused (fESWT) and radial (rESWT). Focused ESWT sends medium to high energy shock waves of a single pressure pulses lasting less than a microsecond directed on a

specific target using ultrasound or radio graphic guidance. A high-dose protocol consists of a single treatment of high-energy shock waves (1300mJ/mm^2). This painful procedure requires anesthesia and usually done as an inpatient procedure. rESWT transmits low to medium energy shockwave radially over a large surface area. A low-dose protocol consists of multiple treatments, spaced one week to one month apart, in which a lower dose of shock waves is applied. This protocol does not require anesthesia.

SUPPORTIVE LITERATURE

There is insufficient data published in the peer-reviewed literature to draw conclusions about the effectiveness of either fESWT or rESWT for treatment of musculoskeletal conditions. Outcomes of trials on clinically relevant measures are inconsistent, and interpretation is complicated by variations in treatment protocols. Published evidence for the use of ESWT to promote healing of fracture non-union consists of several, relatively small, randomized, controlled trials (RCTs) with methodologic limitations, along with reports of case series, and it cannot be concluded from such studies that ESWT results in acceleration of union. Small RCTs have reported a benefit for pain and functional outcomes for tendinopathies, including shoulder and Achilles tendinopathies; however, many trials have been considered to be of poor quality. More high-quality trials are needed, to determine whether ESWT improves net health outcomes.

Also, the available evidence in the medical literature evaluating the safety and efficacy of ESWT for wound healing is insufficient to support its use for this indication at the present time.

Aldajah and colleagues (2022) compared ESWT (n=20) with conventional physiotherapy (n=20) in patients with lateral epicondylitis. All patients received five sessions during the treatment program. Outcome measures included changes in visual analogue (VAS) for pain intensity, the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire for upper extremity function, and dynamometer for maximal grip strength. Patients in both groups improved significantly after treatment in terms of VAS, DASH scores, and maximal grip strength from baseline. The patients in the ESWT arm performed better than those in the physiotherapy arm for all outcomes.

Charles et al. (2023) performed a comprehensive review to identify RCTs that assessed shockwave therapy for specific conditions. Inclusion criteria included adult patients (between ages of 18-70) diagnosed with patellar tendinopathy, Achilles tendinopathies, or plantar fasciitis of any duration and severity, with or without radiological confirmation. Key outcomes that were measure where pain reduction, functional improvement, and overall treatment effectiveness. The study concluded that there is low to moderate evidence that ESWT has a negligible effect on pain and function for patellar tendinopathy and Achilles tendinopathies. There is high-quality evidence that suggests ESWT has a large effect on pain and function for plantar fasciitis. This study emphasized the need for larger scale RCT's to further validate these findings and to establish standard treatment protocols.

Kaplan and colleagues (2023) reported on an investigator-blinded trial that randomized 87 patients with lateral epicondylitis to focused shockwave, radial shock wave, or sham treatment. Both ESWT groups experienced significant reductions in Patient-Rated Tennis Elbow Evaluation (PRTEE) scores from baseline to weeks 5 and 13, the sham group did not demonstrate statistically significant

differences from baseline to week 5 or 13. The difference between sham and both focused and radial shock wave groups was significant for all PRTEE score changes (pain, function, and total). Additionally, focal shock wave was superior to radial shock wave for changes in PRTEE pain, function, and total scores from baseline to weeks 5 and 13.

Otero-Luis et al. (2024) performed a meta-analysis of 14 RCTs and 2 crossover trials evaluating the effect of ESWT on spasticity secondary to various etiologies, including stroke, cerebral palsy, and multiple sclerosis. The control group treatments were not specified. Results demonstrated that ESWT showed significant reductions in spasticity levels as indicated by Modified Ashworth Scale scores, both in upper limbs and lower limbs. At 12 weeks post-intervention, the efficacy of ESWT did not reach statistical significance compared to control. Limitations of this meta-analysis include small sample sizes and heterogeneity due to differences between populations (i.e., age, etiology) and ESWT protocols.

PROFESSIONAL GUIDELINE(S)

National Institute for Health and Care Excellence (NICE) Guidelines

The evidence on ESWT for Achilles tendinopathy, refractory tennis elbow, plantar fasciitis raises no major safety concerns. Current evidence on efficacy of the procedure is inconsistent and limited in quality and quantity. ESWT for Achilles tendinopathy, refractory tennis elbow, plantar fasciitis should only be used with special arrangements for clinical governance, consent and audit or research.

REGULATORY STATUS

The U. S. Food and Drug Administration (FDA) approved the first focused ESWT devices in 2002 and then in 2007 approved radial shockwave devices.

The OssaTron device (HealthTronics, Inc.) was approved by the United States Food and Drug Administration (FDA) in July 2000 for chronic proximal plantar fasciitis and is also approved for use in the treatment of lateral epicondylitis.

Dornier MedTech, Inc. received FDA premarket approval (PMAF) for the Epos Ultra ESWT device on January 15, 2002, for the treatment of plantar fasciitis.

Siemens Healthcare's SONOCUR Basic System was approved in July 2002 for treatment of epicondylitis (tennis elbow).

Orthometrix, Inc.'s Orbasone Pain Relief System and Medispec Sdn Bhd (Malaysia)'s Orthospec, received FDA PMA in 2005; both are approved to treat plantar fasciitis. The FDA-labeled indication for the OssaTron and Epos Ultra devices specifically describes a high-dose protocol, while the labeled indication for the SONOCUR device describes a low-dose protocol.

In May 2007, the Dolorclast from EMS Electro Medical Systems, Nyon, Switzerland, a rESWT, was approved by FDA through the PMA process.

The Sanuwave Health dermaPACE system received FDA clearance on December 28, 2017. This device provides acoustic pressure shockwaves in the treatment of chronic, full-thickness, diabetic foot ulcers

with wound areas measuring no larger than 16 cm^2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure.

The dermaPACE System is indicated for diabetic patients aged 22 years and older who present with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care. The FDA reviewed clinical data from two multi-center, randomized, double-blind studies with a total of 336 diabetic patients receiving either usual care plus the dermaPACE System shockwave therapy or usual care plus sham shockwave therapy. In the first study, 206 subjects were randomized to either dermaPACE (n=107) or to a sham-controlled group (n=99). At the 24-week endpoint, the rate of wound closure in the dermaPACE cohort was 39.3%, compared to 26.3% in the control group. In the second study, 130 subjects were randomized to dermaPACE (n=65) or to a sham-controlled group (n=65). At the 24-week endpoint, the rate of wound closure in the dermaPACE cohort was 35.4%, compared to 26.2% in the control group.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

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

HCPCS Codes

Code	Description
	No specific code(s)

ICD10 Codes

Code	Description
G56.00-G56.03	Carpal tunnel syndrome (code range)
M72.2	Plantar fascial fibromatosis
M75.00-M75.02	Adhesive capsulitis of shoulder (code range)
M75.20-M75.22	Bicipital tendinitis (code range)
M75.30-M75.32	Calcific tendinitis of shoulder (code range)
M77.00-M77.02	Medial epicondylitis (code range)
M77.10-M77.12	Lateral epicondylitis, elbow (code range)
M77.30-M77.32	Calcaneal spur, foot (code range)
M87.051-M87.059	Idiopathic aseptic necrosis of femur (code range)
Multiple ICD10 diagnosis codes for open wounds, burns, and fracture nonunion codes	

REFERENCES

Aldajah S, et al. Analgesic effect of extracorporeal shock wave therapy in individuals with lateral epicondylitis: a randomized controlled trial. J Funct Morphol Kinesiol. 2022 Mar 18;7(1):29.

Avendaño-Coy J, et al. Extracorporeal shockwave therapy improves pain and function in subjects with knee osteoarthritis: A systematic review and meta-analysis of randomized clinical trials. Int J Surg. 2020 Oct;82:64-75.

Chen JM, et al. Functional outcomes of bilateral hip necrosis: total hip arthroplasty versus extracorporeal shockwave. Arch Orthop Trauma Surg. 2009 Jun;129(6):837-41.

ElGendy MH, 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. 2023 Jun 1;102(6):533-540.

Kaplan S, et al. Comparative effects of focused and radial extracorporeal shock wave therapies on lateral epicondylitis: a randomised sham-controlled trial. J Coll Physicians Surg Pak. 2023 May;33(5):554-559.

Kesikburun S, et al. Comparison of ultrasound-guided prolotherapy versus extracorporeal shock wave therapy in the treatment of chronic plantar fasciitis: A randomized clinical trial. J of Foot and Ankle Surgery. 2022; 61: 48-52.

Knobloch K, et al. Focused electromagnetic high-energetic extracorporeal shockwave (ESWT) reduces pain levels in the nodular state of Dupuytren's disease-a randomized controlled trial (DupuyShock). Lasers Med Sci. 2021 Jan 23. [Online ahead of print.]

Marotta N, et al. Effect of radial extracorporeal shock wave therapy in reducing pain in patient with temporomandibular disorders: a pilot randomized controlled trial. Applied Sciences. 2022 Apr;12(8):3821.

National Institute for Health and Clinical Excellence. [Internet] Extracorporeal shockwave therapy for achilles tendinopathy. Interventional procedures guidance [IPG571]. Published: 21 December 2016. [accessed 2025 Feb 12]. Available from: https://www.nice.org.uk/guidance/ipg571

*National Institute for Health and Clinical Excellence. [Internet] Extracorporeal shockwave therapy for refractory plantar fasciitis. Interventional procedures guidance [IPG311]. Published:26 August 2009. [accessed 2025 Feb 12]. Available from: https://www.nice.org.uk/guidance/ipg311

*National Institute for Health and Clinical Excellence. [Internet] Extracorporeal shockwave therapy for refractory tennis elbow. Interventional procedures guidance [IPG313]. Published: 26 August 2009. [accessed 2025 Feb 12]. Available from: https://www.nice.org.uk/guidance/ipg313

National Institute for Health and Clinical Excellence. [Internet] Extracorporeal shockwave therapy for refractory greater trochanter pain syndrome. Interventional procedure [IPG376]. Published: 26 January 2011. [accessed 2025 Feb 12] Available from: https://www.nice.org.uk/guidance/ipg376

National Institute for Health and Clinical Excellence. [Internet] Extracorporeal shockwave therapy for calcific tendinopathy in the shoulder. Interventional procedures guidance [IPG742]. Published: 9 November 2022. [accessed 2025 Feb 12]. Available from: https://www.nice.org.uk/guidance/ipg742

Otero-Luis I, et al. Effectiveness of extracorporeal shock wave therapy in treatment of spasticity of different aetiologies: a systematic review and meta-analysis. J Clin Med. 2024 Feb 26;13(5):1323.

Rai S, et al. Intralesional steroid injection versus extracorporeal shockwave therapy in the treatment of plantar fasciitis: a comparative, prospective, case series study. Cureus. 2023 Jan 10;15(1):e33593.

Charles R, et al. The effectiveness of shockwave therapy on patellar tendinopathy, Achilles tendinopathy, and plantar fasciitis: a systematic review and meta-analysis. Front Immunol. 2023 Aug 16;14:1193835.

Rhim HC, et al. A systematic review of systematic reviews on the epidemiology, evaluation, and treatment of plantar fasciitis. Life (Basel). 2021 Nov 24;11(12):1287.

Sagla, G et al. Physical therapy versus radial extracorporeal shock wave therapy in the treatment of carpal tunnel syndrome: A randomized-controlled study. Turk J Phys Med Rehabil. 2022 Mar 1;68(1):126-135.

Stolberg-Stolberg J, et al. Addition of shock wave therapy to nail dynamization increases the chance of long-bone non-union healing. J Orthop Traumatol. 2022 Jan 8;23(1):4.

U.S. Food and Drug Administration (FDA). [Internet] Device classification Under Section 513 (f)(2)(De Novo). De Novo Classification Extracorporeal Shock Wave Device for Treatment of Diabetic Foot Ulcers [accessed 2025 Feb 12]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN160037

Zhang YF, et al. Dose-related effects of radial extracorporeal shock wave therapy for knee osteoarthritis: A randomized controlled trial. J Rehabil Med. 2021 Jan 13;53(1):jrm00144.

SEARCH TERMS

Lithotripsy, Orthotripsy, Ossatron, extracorporeal pulse activation therapy (EPAT), extracorporeal acoustic wave therapy, pulsed acoustic cellular expression (PACE) therapy.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based on our review, extracorporeal shock wave therapy for musculoskeletal conditions is not addressed in National Medicare coverage determinations or policies.

LCD - Extracorporeal Shock Wave Therapy (ESWT) (L38775) [accessed 2025 Feb 12].

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

02/21/02, 02/20/03, 02/19/04, 02/17/05, 12/15/05, 01/18/07, 10/18/07, 09/18/08, 08/20/09, 07/15/10, 06/16/11, 06/21/12, 08/15/13, 07/17/14, 06/18/15, 06/16/16, 06/15/17, 06/21/18, 05/16/19, 03/19/20, 03/18/21, 03/24/22, 03/23/23, 03/21/24, 03/20/25

Date	Summary of Changes
03/20/25	• Annual review, policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
10/18/01	• Original effective date