

# MEDICAL POLICY

Medical Policy Title	<b>Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds</b>
Policy Number	<b>2.01.31</b>
Current Effective Date	<b>March 19, 2026</b>
Next Review Date	<b>March 2027</b>

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.

(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 promote healing of musculoskeletal and soft tissue injuries. ESWT is also known as orthotripsy and was initially developed as kidney stones treatment and has been investigated for 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 ESWT might influence 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 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

## **Medical Policy: Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds**

**Policy Number: 02.01.31**

**Page: 2 of 8**

high energy shock waves of 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<sup>2</sup>). 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**

Pisirici et al (2022) published a randomized controlled trial (RCT) that compared ESWT with instrument-assisted soft-tissue mobilization using Graston technique (GT) to treat chronic plantar heel pain (CPHP). Participants (n=69) were assigned to either the ESWT and stretching exercise (SE) group 1, the GT and SE group 2, or the SE only control group 3. Each group completed SE twice daily for 8 weeks. The measured outcomes of the visual analog scale and the Foot Function Index (FFI) improved in all groups. At 6 months follow-up, group 2 showed significant improvements in FFI scores compared with the other 2 groups. The authors concluded that the soft tissue mobilization with the Graston instrument was found most effective for improving functional status for CPHP.

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 measured were 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,

## **Medical Policy: Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds**

**Policy Number: 02.01.31**

**Page: 3 of 8**

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.

Hitchman et al (2025) published results of a double-blind, RCT that aimed to treat diabetic foot ulcers (DFU) with ESWT. Patients (n=74) with a DFU present for  $\geq 4$  weeks were randomized to high dose (n=25), low dose (n=23), or sham (n=26) ESWT, plus standard care. At 24 weeks, 64.0% (16/25) of DFUs healed in the high dose ESWT arm, 56.5% (13/23) healed in the low dose arm and 42.3% (11/26) healed in the sham arm. Limitations of the study include a small sample size and baseline differences between the study arms such as patient age, duration of diabetes and/or DFU, and DFU size. DFU infection information was not collected during the study. The authors conclude that the results of this pilot RCT signal that ESWT, especially high dose ESWT, may be associated with accelerated healing compared to standard care alone. They recommend further high powered RCT to explore the efficacy of different doses of ESWT to augment DFU healing.

### **PROFESSIONAL GUIDELINE(S)**

National Institute for Health and Care Excellence (NICE) published guidance for ESWT for refractory tennis elbow (2009). They found the evidence of efficacy inadequate stating, "The results of studies conflicted and there was evidence of a substantial placebo response."

NICE guidance for ESWT for refractory plantar fasciitis (2009) states "ESWT for refractory plantar fasciitis raises no major safety concerns; however, current evidence on its efficacy is inconsistent."

NICE guidance for ESWT for Achilles tendinopathy (2016) states "ESWT for Achilles tendinopathy raises no major safety concerns. Current evidence on efficacy of the procedure is inconsistent and limited in quality and quantity."

NICE guidance for ESWT for refractory greater trochanteric pain syndrome (2011) states "evidence on the efficacy and safety of extracorporeal shockwave therapy (ESWT) for refractory greater trochanteric pain syndrome is limited in quality and quantity."

NICE guidance for ESWT for calcific tendinopathy in the shoulder (2022) states "evidence on the safety of extracorporeal shockwave therapy for calcific tendinopathy in the shoulder shows no major safety concerns in the short term. Evidence on efficacy is inadequate. Therefore, this procedure should only be used in the context of research."

American College of Foot and Ankle Surgeons published a clinical consensus statement regarding the diagnosis and treatment of adult acquired infracalcaneal heel pain (Schneider 2018). They state that ESWT is safe and effective in the treatment of plantar fasciitis.

## **Medical Policy: Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds**

**Policy Number: 02.01.31**

**Page: 4 of 8**

The International Society for Medical Shockwave Treatment's ESWT Guidelines (2023) recommend ESWT for calcific tendinopathy of the shoulder, lateral epicondylopathy of the elbow (tennis elbow), Dupuytren's disease, Greater trochanter pain syndrome (GTPS), plantar fasciitis, Achilles tendinopathy, patellar tendinopathy, Tibial stress syndrome (TSS), hamstring tendinopathy, Ledderhose disease as plantar fibromatosis, osteoarthritis – knee osteoarthritis, osteochondrosis dissecans, bone marrow edema, pseudoarthrosis and delayed healing bone fractures, stress fractures, aseptic femoral head necrosis, delayed or non-healing wounds, skin ulcers, non-circumferential burn wounds, cellulite, induration penis plastica, erectile dysfunction, chronic pelvic pain, and spasticity.

### **REGULATORY STATUS**

The U.S. Food and Drug Administration (FDA) regulates ESWT as medical devices. All ESWT devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: <https://www.fda.gov/medical-devices> [accessed 2026 Feb 2]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls-and-early-alerts> [accessed 2026 Feb 2]

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<sup>2</sup>, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure.

## Medical Policy: Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds

Policy Number: 02.01.31

Page: 5 of 8

### 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, and involving the lateral humeral epicondyle
0512T (E/I)	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; initial wound
0513T (E/I)	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 (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

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### HCPCS Codes

Code	Description
Not Applicable	

### ICD10 Codes

Code	Description
Multiple Codes	

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## **Medical Policy: Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds**

**Policy Number: 02.01.31**

**Page: 6 of 8**

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## **Medical Policy: Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds**

**Policy Number: 02.01.31**

**Page: 7 of 8**

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# Medical Policy: Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds

Policy Number: 02.01.31

Page: 8 of 8

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## SEARCH TERMS

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

## CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

[Extracorporeal Shock Wave Therapy \(ESWT\) \(LCD L38775\)](#) [accessed 2026 Feb 2].

[Billing and Coding: Extracorporeal Shock Wave Therapy \(ESWT\) \(Article A58367\)](#) [accessed 2026 Feb 2].

## 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

10/18/01, 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, 03/19/26

### Date

### Summary of Changes

03/19/26

- Annual review, policy intent unchanged.

03/20/25

- Annual review, policy intent unchanged.

01/01/25

- Summary of changes tracking implemented.

10/18/01

- Original effective date