BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 2.01.40 Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

Annual Effective Policy Date: October 1, 2025

Original Policy Date: December 2011

Related Policies:

1.01.05 - Low Intensity Pulsed Ultrasound Fracture Healing Device
7.01.07 - Electrical Bone Growth Stimulation of the Appendicular Skeleton

Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

Description

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Extracorporeal shock wave therapy (ESWT) is a noninvasive method used to treat pain with shock or sound waves directed from outside the body onto the area to be treated (eg, the heel in the case of plantar fasciitis). Shock waves are generated at high- or low-energy intensity, and treatment protocols can include more than 1 treatment. ESWT has been investigated for use in a variety of musculoskeletal conditions.

Other mechanisms are also thought to be involved in ESWT. Physical stimuli are known to activate endogenous pain control systems, and activation by shock waves may "reset" the endogenous pain receptors. Damage to endothelial tissue from ESWT may result in increased vessel wall permeability, causing increased diffusion of cytokines, which may, in turn, promote healing. Microtrauma induced by ESWT may promote angiogenesis and thus aid healing. Finally, shock waves have been shown to stimulate osteogenesis and promote callous formation in animals, which is the basis for trials of ESWT in delayed union or nonunion of bone fractures.

There are 2 types of ESWT: focused and radial. Focused ESWT sends medium- to high-energy shockwaves of single pressure pulses lasting microseconds, directed on a specific target using ultrasound or radiographic guidance. Radial ESWT (RSW) transmits low- to medium-energy shockwaves radially over a larger surface area. The U.S. Food and Drug Administration (FDA) approval was first granted in 2002 for focused ESWT devices and in 2007 for RSW devices.

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OBJECTIVE

The objective of this evidence review is to examine whether the use of extracorporeal shock wave treatment for plantar fasciitis, lateral epicondylitis, tendinopathy (shoulder, Achilles, and patellar), medial tibial stress syndrome, osteonecrosis of the femoral head, acute fracture nonunion or delayed union, or spasticity improves the net health outcome.

POLICY STATEMENT

Extracorporeal shock wave therapy using either a high- or low-dose protocol or radial extracorporeal shock wave therapy is considered **not medically necessary** as a treatment of musculoskeletal conditions, including but not limited to plantar fasciitis; tendinopathies including tendinitis of the shoulder, Achilles tendinitis, tendinitis of the elbow (lateral epicondylitis), and patellar tendinitis; stress fractures; avascular necrosis of the femoral head; delayed union and nonunion of fractures; and spasticity.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Extracorporeal shock wave treatment for plantar fasciitis may be performed by podiatrists, orthopedic surgeons, and primary care physicians.

FDA REGULATORY STATUS

Selected ESWT devices that have been approved or cleared by FDA are included in Table 1.

Table 1. Food and Drug Administration-approved Extracorporeal Shock Wave Therapy Devices

Device Name	Approval Date	Delivery System Type	Indication
OssaTron device (HealthTronics)	2000	Electrohydraulic delivery system	• Chronic proximal plantar fasciitis, ie, pain persisting >6 mo and unresponsive to conservative management • Lateral epicondylitis
Epos™ Ultra (Dornier)	2002	Electromagnetic delivery system	Plantar fasciitis

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Sonocur Basic (Siemens)	2002	Electromagnetic delivery system	Chronic lateral epicondylitis (unresponsive to conservative therapy for >6 mo)
Orthospec™ Orthopedic ESWT (Medispec)	2005	Electrohydraulic spark-gap system	Chronic proximal plantar fasciitis in patients ≥18 y
Orbasone™ Pain Relief System (Orthometrix)	2005	High-energy sonic wave system	Chronic proximal plantar fasciitis in patients ≥18 y
Duolith SD1 Shock Wave Therapy Device (Storz Medical AG)	2016	Electromagnetic delivery system	Chronic proximal plantar fasciitis in patients ≥18 y with history of failed alternative conservative therapies >6 mo

Both high-dose and low-dose protocols have been investigated. A high-dose protocol consists of a single treatment of high-energy shock waves (1300 mJ/mm^2). This painful procedure requires anesthesia. A low-dose protocol consists of multiple treatments, spaced 1 week to 1 month apart, in which lower dose shock waves are applied. This protocol does not require anesthesia. 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 2007, Dolorclast (EMS Electro Medical Systems), a radial ESWT, was approved by FDA through the premarket approval process. Radial ESWT is generated ballistically by accelerating a bullet to hit an applicator, which transforms the kinetic energy into radially expanding shock waves. Radial ESWT is described as an alternative to focused ESWT and is said to address larger treatment areas, thus providing potential advantages in superficial applications like tendinopathies. The FDA approved indication is for the treatment of patients 18 years and older with chronic proximal plantar fasciitis and a history of unsuccessful conservative therapy.

RATIONALE

Summary of Evidence

For treatment of plantar fasciitis using extracorporeal shock wave therapy (ESWT), numerous randomized controlled trials (RCTs) were identified, including several well-designed, double-blind RCTs, that evaluated ESWT for the treatment of plantar fasciitis. Several systematic reviews and meta-analyses have been conducted, covering numerous studies, including studies that compared ESWT with corticosteroid injections and other treatment modalities. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Pooled results were inconsistent. Some meta-analyses reported that ESWT reduced pain, while others reported nonsignificant pain reduction. Reasons for the differing results included lack of uniformity in the definitions of outcomes and heterogeneity in ESWT protocols (focused vs. radial, low-vs. high-intensity/energy, number and duration of shocks per treatment, number of treatments, and differing comparators). Some studies reported significant benefits in pain and functional improvement at 3 months, but it is not evident that the longer-term disease natural history is altered with ESWT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lateral epicondylitis who receive ESWT, the most direct evidence on the use of ESWT to treat lateral epicondylitis comes from multiple small RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The RCTs did not consistently show outcome improvements beyond those seen in control groups. The highest quality trials tend to show no benefit, and systematic reviews have generally concluded that the evidence does not support a treatment benefit over placebo or no treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have shoulder tendinopathy who receive ESWT, a number of small RCTs, summarized in several systematic reviews and meta-analyses, comprise the evidence. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Network meta-analyses focused on 3 outcomes: pain reduction, functional assessment, and change in calcific deposits. One network meta-analysis separated trials using high-energy focused shock wave (H-FSW), low-energy focused shock wave, and radial shock wave (RSW). It reported that the most effective treatment for pain reduction was ultrasound-guided needling, followed by RSW and H-FSW. The only treatment showing a benefit in functional outcomes was H-FSW. For the largest change in calcific deposits, the most effective treatment was ultrasound-guided needling followed by RSW and H-FSW. Although some trials have reported a benefit for pain and functional outcomes, particularly for high-energy ESWT for calcific tendinopathy, many available trials have been considered poor quality. For non-calcific tendinopathy, 1 meta-analysis found that ESWT exhibited a small improvement in shoulder pain compared to sham ESWT at short-term follow-up (≤3 months). However, ESWT was not superior to sham ESWT in improving function at short- or long-term follow up (≥12 months), and ESWT was not superior to other treatments. More high-quality trials are needed to determine whether ESWT improves outcomes for shoulder tendinopathy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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For individuals who have Achilles tendinopathy who receive ESWT, the evidence includes systematic reviews of RCTs and RCTs published after the systematic review. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. In a recent systematic review, a pooled analysis found that ESWT reduced both short- and long-term pain compared with nonoperative treatments, although reviewers warned that results were inconsistent across the RCTs and that there was heterogeneity across patient populations and treatment protocols. A RCT published after the systematic review compared ESWT with hyaluronan injections and reported improvements in both treatment groups, although the improvements were significantly higher in the injection group. A RCT found no difference in pain scores between low-energy ESWT and sham controls at week 24, but ESWT may provide short therapeutic effects at weeks 4 to 12. Another RCT found scores were statistically and clinically improved with ESWT compared with sham control at 1 month and 16 months on measures of pain and function. recent RCT found that activity-related pain was lower with ESWT at 6 weeks compared to ultrasound therapy, but there was no difference in pain at rest. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have patellar tendinopathy who receive ESWT, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Systematic reviews and trials have reported inconsistent results and were heterogeneous in treatment protocols and lengths of follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have medial tibial stress syndrome who receive ESWT, the evidence includes a small RCT and a small nonrandomized cohort study. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The RCT showed no difference in self-reported pain measurements between study groups. The nonrandomized trial reported improvements with ESWT, but selection bias limited the strength of the conclusions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have osteonecrosis of the femoral head who receive ESWT, the evidence includes systematic reviews of small, mostly nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Many of the studies were low quality and lacked comparators. While most studies reported favorable outcomes with ESWT, limitations such as heterogeneity in the treatment protocols, patient populations, and lengths of follow-up make conclusions on the efficacy of ESWT for osteonecrosis uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have nonunion or delayed union who receive ESWT, the evidence includes systematic reviews, relatively small RCTs with methodologic limitations (eg, heterogeneous outcomes and treatment protocols), and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The available evidence does not permit conclusions on the efficacy of ESWT in fracture nonunion, delayed union, or acute long bone fractures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have spasticity who receive ESWT, the evidence includes RCTs and systematic reviews, primarily in patients with stroke and cerebral palsy. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Several studies have demonstrated improvements in spasticity measures after ESWT, but most studies have small sample sizes and single center designs. More well-designed controlled trials in larger populations are needed to determine whether ESWT leads to clinically meaningful improvements in pain and/or functional outcomes for spasticity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Foot and Ankle Surgeons

In 2010, Thomas et al revised guidelines on the treatment of heel pain on behalf of the American College of Foot and Ankle Surgeons.[119,] The guidelines identified extracorporeal shock wave therapy (ESWT) as a third tier treatment modality in patients who have failed other interventions, including steroid injection. The guidelines recommended ESWT as a reasonable alternative to surgery. In an update to the American College of Foot and Ankle Surgeons clinical consensus statement, Schneider et al stated that ESWT is a safe and effective treatment for plantar fasciitis.[120,]

National Institute for Health and Care Excellence

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The NICE has published guidance on ESWT for a number of applications.

- The 2 guidance documents issued in 2009 stated that current evidence on the efficacy of ESWT for refractory tennis elbow and plantar fasciitis "is inconsistent".[121,122,]
- A guidance issued in 2011 stated that evidence on the efficacy and safety of ESWT for refractory greater trochanteric pain syndrome "is limited in quality and quantity".[123,]
- A guidance issued in 2016 stated that current evidence on the efficacy of ESWT for Achilles tendinopathy "is inconsistent and limited in quality and quantity".[124,]
- A guidance issued in 2022 stated that evidence on the efficacy of ESWT for calcific tendinopathy of the shoulder is inadequate. Despite a lack of safety concerns, the ESWT should only be used in the context of research.[125,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	ESWT is not medically necessary
June 2013	Replace policy	Policy updated with literature review, references 11, 19, 20, 21, 24, 25 and 36 added; some references removed. No change to policy statements. Related policies added.
June 2014	Replace policy	Policy updated with literature review, references 5-7, 24-25, 30 and 34 added. No change to policy statement.
June 2015	Replace policy	Policy updated with literature review; References 8, 15, 17, 28, 31, 34, 40, 45, 47-48, and 54-55 added. Editorial changes made for clarity to policy statements; intent of policy statements unchanged
December 2016	Replace policy	Policy updated with literature review through May 2, 2016; references 9, 27-28, and 30 added. Policy statements unchanged.
September 2018	Replace policy	Policy updated with literature review through April 30, 2018; references 5-6, 18, 20-22, 27, 34-35, 37, 41-43, 45-46, 51-53, 56-58, 61, 64, 68 and 79. Policy statement unchanged.
September 2019	Replace policy	Policy updated with literature review through April 3, 2019; references added. Policy statement unchanged.
December 2020	Replace policy	Policy updated with literature review through September 2, 2020; references added. Policy statement unchanged.
September 2021	Replace policy	Policy updated with literature review through April 21, 2021; references added. Policy statement unchanged.
September 2022	Replace policy	Policy updated with literature review through May 2, 2022; references added. Policy statement unchanged.
September 2023	Replace policy	Policy updated with literature review through April 21, 2023; references added. Policy statement unchanged.
September 2025	Replace policy	Policy updated with literature review through April 18, 2025; references added. Policy statement unchanged.

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