Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

Description

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.

Also known as orthotripsy, extracorporeal shock wave therapy (ESWT) has been available since the early 1980s for the treatment of renal stones and has been widely investigated for the treatment of biliary stones. ESWT uses externally applied shock waves to create a transient pressure disturbance, which disrupts solid structures, breaking them into smaller fragments, thus allowing spontaneous passage and/or removal of stones. The mechanism by which ESWT might have an effect on musculoskeletal conditions is not well-defined.

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 Food and Drug Administration (FDA) approval was first granted in 2002 for focused ESWT devices and in 2007 for RSW devices.

**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.

**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**

Currently, 6 focused ESWT devices have been approved by FDA through the premarket approval process for orthopedic use (see Table 1). FDA product code: NBN.

Table 1. FDA-Approved Extracorporeal Shock Wave Therapy Devices

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Approval Date</th>
<th>Delivery System Type</th>
<th>Indication</th>
</tr>
</thead>
</table>
| 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                                                         |
| 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                         |

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<table>
<thead>
<tr>
<th>Device and Manufacturer</th>
<th>Year</th>
<th>Technology</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orbasone™ Pain Relief System (Orthometrix)</td>
<td>2005</td>
<td>High-energy sonic wave system</td>
<td>Chronic proximal plantar fasciitis in patients ≥18 y</td>
</tr>
<tr>
<td>Duolith SD1 Shock Wave Therapy Device (Storz Medical AG)</td>
<td>2016</td>
<td>Electromagnetic delivery system</td>
<td>Chronic proximal plantar fasciitis in patients ≥18 y with history of failed alternative conservative therapies &gt;6 mo</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration.

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/mm²). 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. FDA product code: NBN.

**Rationale**

**Summary of Evidence**

For treatment of plantar fasciitis using ESWT, numerous RCTs were identified, including several well-designed double-blinded RCTs, that evaluated ESWT for the treatment of plantar fasciitis. Seven systematic reviews and meta-analyses have been conducted, covering a total of 27 studies. 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 three months, but it is not evident that the longer-term disease natural history is altered with ESWT. Currently, it is not possible to conclude definitively that ESWT improves outcomes for patients with plantar fasciitis.

For individuals who have lateral epicondylitis who receive ESWT, the evidence includes small RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Overall, although some RCTs have demonstrated benefits in pain and functional outcomes associated with ESWT, the limited amount of high-quality RCT evidence precludes conclusions about the efficacy of ESWT for lateral epicondylitis. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have shoulder tendinopathy who receive ESWT, the evidence includes 2 network meta-analyses as well as several systematic reviews and meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The 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 ESWT (H-FSW), low-energy ESWT, and radial ESWT (RSW). This analysis reported 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, then H-FSW. Many of the RCTs were judged of poor quality. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have Achilles tendinopathy who receive ESWT, the evidence includes systematic reviews of RCTs, an RCT published after the systematic review, and nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. In the most 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 studies (eg, patient populations, treatment protocols). An 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have patellar tendinopathy who receive ESWT, the evidence includes systematic reviews of small studies, an RCT published after the systematic review, and a nonrandomized study. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The studies reported inconsistent results. Many had methodologic deficiencies such as small numbers, short follow-up periods, and heterogeneous treatment protocols. Results from a nonrandomized study suggested that the location of the patellar tendinopathy might impact the response to ESWT (patients with retropatella fat extension did not respond to RSW compared with patients with tendon involvement). The evidence is insufficient to determine the effects of the technology on health outcomes.

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 reported no difference in self-reported pain between study groups. The cohort study reported improvements with ESWT, although selection bias impacted the strength of the conclusions. The available evidence is limited and inconsistent; it does not permit conclusions about the benefits of ESWT for medial tibial stress syndrome. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have osteonecrosis of the femoral head who receive ESWT, the evidence includes 2 systematic reviews of small, mostly nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. While many of the studies have suggested that ESWT might be effective in improving motor function and reducing pain, particularly in patients with early-stage osteonecrosis, the studies were judged of low quality based on lack of blinding, lack of comparators, small sample sizes, short follow-up, and variations in treatment protocols. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have nonunion or delayed union who receive ESWT, the evidence includes a systematic review of an RCT and several case series, as well as 2 RCTs published after the systematic review. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Reviewers concluded that the evidence was inconsistent and of poor quality. Data pooling was not possible due to the heterogeneity of outcome definitions and treatment protocols. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have spasticity who receive ESWT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. As a treatment for spasticity, several small studies have demonstrated ESWT provides short-term improvements in Modified Ashworth Scale scores, but direct evidence on the effect of ESWT on more clinically meaningful measures (e.g., pain, function) are lacking. Differences in treatment parameters among studies, including energy dosage, method of generating and directing shock waves, and use or absence of anesthesia, limit generalizations about the evidence base. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 reported no difference in self-reported pain between study groups. The cohort study reported improvements with ESWT, although selection bias impacted the strength of the conclusions. The available evidence is limited and inconsistent; it does not permit conclusions about the benefits of ESWT for medial tibial stress syndrome. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Foot and Ankle Surgeons

Thomas et al (2010) revised guidelines on the treatment of heel pain on behalf of the American College of Foot and Ankle Surgeons. 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 (2018) state that ESWT is a safe and effective treatment for plantar fasciitis.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence has published guidance on ESWT for a number of applications.

• A guidance issued in 2003 stated that current evidence on safety and efficacy for treatment of calcific tendonitis of the shoulder "appears adequate to support the use of the procedure."

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• 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." 79, 80,

• 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." 81,

• 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." 82.

**Canadian Agency for Drugs and Technologies in Health**

A 2007 summary by the Canadian Agency for Drugs and Technologies in Health (CADTH) noted that results from randomized trials of ESWT for plantar fasciitis have been conflicting. 83, The report noted that the "lack of convergent findings from randomized trials of ESWT for chronic plantar fasciitis suggests uncertainty about its effectiveness. The evidence reviewed ... does not support the use of this technology for this condition."

Similarly, a 2007 report by CADTH on ESWT for chronic lateral epicondylitis noted conflicting results from randomized trials (RCTs), with half showing no benefit over placebo for any outcome measures 84. The report noted that "the lack of convincing evidence regarding its effectiveness does not support the use of ESWT for CLE [chronic lateral epicondylitis]."

A third 2007 summary by CADTH concluded that "the current evidence supports the use of high-energy ESWT for chronic calcific rotator cuff tendonitis that is recalcitrant to conventional conservative treatment, although more high-quality RCTs with larger sample sizes are required to provide more convincing evidence." 85.

A 2016 update from CADTH addressed the use of shockwave therapy for pain associated with upper- extremity orthopedic disorders. 86. Based on results from 7 systematic reviews (with overlapping randomized controlled trials), the Agency concluded the following (see Table 2).

**Table 2. Conclusions on the Use of ESWT for Upper-Extremity Pain**

<table>
<thead>
<tr>
<th>Condition</th>
<th>Evidence</th>
<th>Comparator</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shoulder</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcific tendonitis</td>
<td>Systematic reviews</td>
<td>Placebo</td>
<td>Effective in reducing pain</td>
</tr>
<tr>
<td>Noncalcific tendonitis</td>
<td>Systematic reviews</td>
<td>Placebo or other treatments</td>
<td>No significant benefit</td>
</tr>
<tr>
<td>Tendonitis</td>
<td>Single RCTs</td>
<td>Exercise or radiotherapy</td>
<td>No significant benefit</td>
</tr>
<tr>
<td>Tendonitis</td>
<td>1 RCT</td>
<td>Transcutaneous electric nerve stimulation</td>
<td>Effective in reducing pain</td>
</tr>
<tr>
<td>Elbow</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lateral epicondylitis</td>
<td>Systematic reviews</td>
<td>Placebo</td>
<td>Inconclusive</td>
</tr>
<tr>
<td>Lateral epicondylitis</td>
<td>Single RCTs</td>
<td>Physical therapy or percutaneous tenotomy</td>
<td>No significant benefit</td>
</tr>
</tbody>
</table>

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Lateral epicondylitis | Single RCTs | Corticosteroid injections | Inconclusive

ESWT: extracorporeal shockwave treatment; RCT: randomized controlled trial.

**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.

**REFERENCES**


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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tr>
<td>December 2011</td>
<td>New policy</td>
<td>Not medically necessary</td>
</tr>
<tr>
<td>June 2013</td>
<td>Replace policy</td>
<td>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.</td>
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<tr>
<td>June 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review, references 5-7, 24-25, 30 and 34 added. No change to policy statement.</td>
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<tr>
<td>June 2015</td>
<td>Replace policy</td>
<td>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</td>
</tr>
<tr>
<td>December 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review through May 2, 2016; references 9, 27-28, and 30 added. Policy statements unchanged.</td>
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<tr>
<td>September 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through April 3, 2019; references added. Policy statement unchanged.</td>
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