Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

Policy #  00039
Original Effective Date:  08/27/2001
Current Effective Date:  03/15/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers extracorporeal shockwave therapy (ESWT), using either a high-dose or low-dose protocol or radial extracorporeal shockwave therapy (rESWT), as a treatment of musculoskeletal conditions to be investigational*, including but not limited to:

- Plantar fasciitis;
- Tendinopathies including tendinitis of the shoulder;
- Tendinitis of the elbow (lateral epicondylitis, tennis elbow);
- Achilles tendinitis;
- Patellar tendinitis;
- Spasticity;
- Stress fractures;
- Delayed union and non-union of fractures;
- Avascular necrosis of the femoral head.

Background/Overview
Extracorporeal shock wave therapy is a noninvasive method that may be used to treat pain using shock waves or sound waves. These waves are directed from outside the body onto the area to be treated, the heel in the case of plantar fasciitis. Shock waves may be generated at high or low energy intensity, and treatment protocols may include more than one treatment. Extracorporeal shock wave therapy has been investigated for use in a variety of musculoskeletal conditions.

Extracorporeal shock wave therapy, also known as orthotripsy, has been available since the early 1980s for the treatment of renal stones and has been widely investigated for the treatment of biliary stones. Extracorporeal shock wave therapy 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. Chronic musculoskeletal conditions (eg, tendinitis) can be associated with a substantial degree of scarring and calcium deposition. Calcium deposits may restrict motion and encroach on other structures, such as nerves and blood vessels, causing pain and decreased function. One hypothesis is that disruption of these calcific deposits by shock waves may loosen adjacent structures and promote resorption of calcium, thereby decreasing pain and improving function.

Other mechanisms are also thought to be involved. Physical stimuli are known to activate endogenous pain control systems and activation by shock waves may “reset” the endogenous pain receptors. Damage to
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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 in healing. Finally, shock waves have been shown to stimulate osteogenesis and promote callous formation in animals, which is the rationale for trials of ESWT in delayed union or non-union of bone fractures.

Plantar Fasciitis
Plantar fasciitis is a very common ailment characterized by deep pain in the plantar aspect of the heel, particularly on arising from bed. While the pain may subside with activity, in some patients the pain may persist, interrupting activities of daily living. On physical examination, firm pressure will elicit a tender spot over the medial tubercle of the calcaneus. The exact etiology of plantar fasciitis is unclear, although repetitive injury is suspected. Heel spurs are a common associated finding, although it has never been proven that heel spurs cause the pain and asymptomatic heel spurs can be found in up to 10% of the population. Most cases of plantar fasciitis are treated with conservative therapy, including rest or minimization of running and jumping, heel cups, and nonsteroidal-anti-inflammatory drugs. Local steroid injection may also be used. Improvement may take up to 1 year in some cases.

Tendinitis and Tendinopathies
ESWT has been investigated for a variety of tendinitis/tendinopathy syndromes. Some of the more common tendinitis syndromes are summarized in Table 1. Many tendinitis/tendinopathy syndromes are related to overuse injury. Conservative treatment often involves rest, activity modifications, physical therapy, and anti-inflammatory medications.

Table 1: Tendinitis/Tendinopathy Syndromes

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Location</th>
<th>Symptoms</th>
<th>Conservative Therapy</th>
<th>Other Therapies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lateral epicondylitis</td>
<td>Lateral elbow (insertion of wrist extensors)</td>
<td>Tenderness over lateral epicondyle and proximal wrist extensor muscle mass; pain with resisted wrist extension with the elbow in full extension; pain with passive terminal wrist flexion with the elbow in full extension</td>
<td>• Rest</td>
<td>Corticosteroid injections; joint débridement (open or laparoscopic)</td>
</tr>
<tr>
<td>(elbow tendinitis/ “tennis elbow”)</td>
<td></td>
<td></td>
<td>• Activity modification</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• NSAIDs</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Physical therapy</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Orthotic devices</td>
<td></td>
</tr>
<tr>
<td>Shoulder tendinopathy</td>
<td>Rotator cuff muscle tendons, most commonly supraspinatus</td>
<td>Pain with overhead activity</td>
<td>• Rest</td>
<td>Corticosteroid injections</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Ice</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• NSAIDs</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Physical therapy</td>
<td></td>
</tr>
<tr>
<td>Achilles tendinopathy</td>
<td>Achilles tendon</td>
<td>Pain or stiffness 2-6 cm above the posterior calcaneus</td>
<td>• Avoidance of aggravating activities</td>
<td>Surgical repair for tendon rupture</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Icing when symptomatic</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• NSAIDs</td>
<td></td>
</tr>
</tbody>
</table>
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Patellar tendinopathy (“jumper’s knee”)
Proximal tendon at lower pole of the patella
Pain over anterior knee and patellar tendon; may progress to tendon calcification and/or tear

- Heel lift
- Icing
- Supportive taping
- Patellar tendon straps
- NSAIDs

Patellar tendinopathy
Proximal tendon at lower pole of the patella
Pain over anterior knee and patellar tendon; may progress to tendon calcification and/or tear

NSAIDs: nonsteroidal anti-inflammatory drugs.

Fracture Nonunion and Delayed Union
The definition of a fracture nonunion has remained controversial, particularly in the necessary duration to define a condition of nonunion. One proposed definition is failure of progression of fracture-healing for at least 3 consecutive months (and at least 6 months following the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing). For purposes of policy development, the following criteria have been used to define nonunion:

- At least 3 months have passed since the date of fracture;
- Serial radiographs have confirmed that no progressive signs of healing have occurred;
- The fracture gap is 1 cm or less; and
- The patient can be adequately immobilized and is of an age likely to comply with non-weight bearing.

Delayed union can be defined as a decelerating healing process, as determined by serial radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention. (In contrast, nonunion serial radiographs show no evidence of healing.)

Other Musculoskeletal and Neurologic Conditions
ESWT has been investigated for a variety of other musculoskeletal conditions, including medial tibial stress syndrome, osteonecrosis (avascular necrosis) of the femoral head, coccydynia, and painful stump neuromas.

Spasticity refers to a motor disorder characterized by increased velocity-dependent stretch reflexes. It is one characteristic of upper motor neuron dysfunction, which may be due to a variety of pathologies.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
Currently, six ESWT devices are approved for marketing by the FDA and are summarized in Table 2.

Table 2: 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>
<tbody>
<tr>
<td>OssaTron® device</td>
<td>2000</td>
<td>Electrohydraulic delivery system</td>
<td>Chronic proximal plantar fasciitis, ie, pain persisting &gt;6 mo and unresponsive to conservative management</td>
</tr>
<tr>
<td>(HealthTronics, Marietta, GA)</td>
<td></td>
<td></td>
<td>Lateral epicondylitis</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Device Type</th>
<th>Year</th>
<th>Delivery System</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epos Ultra</td>
<td>2002</td>
<td>Electromagnetic</td>
<td>Plantar fasciitis</td>
</tr>
<tr>
<td>Sonocur Basic</td>
<td>2002</td>
<td>Electromagnetic</td>
<td>Chronic lateral epicondylitis (unresponsive to conservative therapy for &gt;6 mo)</td>
</tr>
<tr>
<td>Orthospec Orthopedic ESWT</td>
<td>2005</td>
<td>Electrohydraulic spark-gap system</td>
<td>Chronic proximal plantar fasciitis in patients ≥18 y</td>
</tr>
<tr>
<td>Orbasone Pain Relief System</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</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 one week to one month apart, in which a lower dose of shock waves is applied. This protocol does not require anesthesia. The FDA-labeled indication for the OssaTron and Epos Ultra device specifically describes a high-dose protocol, while the labeled indication for the SONOCUR device describes a low-dose protocol.

Another type of ESWT, radial ESWT received pre-market approval (PMA) in May 2007. The FDA-approved device is the Dolorclast from EMS Electro Medical Systems, Nyon, Switzerland. Radial ESWT is generated ballistically by accelerating a bullet to hit an applicator, which transforms the kinetic energy into radially expanding shock waves. Other types of ESWT produce focused shock waves that show deeper tissue penetration with significantly higher energies concentrated to a small focus. 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.

Centers for Medicare and Medicaid Services (CMS)  
No national coverage determination.

**Rationale/Source**  
This policy was based on a 2001 TEC Assessment that concluded that ESWT met TEC criteria as a treatment for plantar fasciitis in patients who had not responded to conservative therapies. A 2003 TEC Assessment reviewed subsequent literature on ESWT for musculoskeletal conditions with a focus on 3 conditions: plantar fasciitis, tendinitis of the shoulder, and tendinitis of the elbow. The 2003 TEC Assessment came to different conclusions, specifically, that ESWT did not meet TEC criteria as a treatment of plantar fasciitis or other musculoskeletal conditions. In 2004, updated TEC Assessments were completed for plantar fasciitis and tendinitis of the elbow. The 2004 TEC Assessments concluded that ESWT did not meet TEC criteria for the treatment of these conditions. Since the 2004 TEC Assessments, this evidence review has been updated periodically with literature searches using the MEDLINE database. The most recent literature review covers the period through May 2, 2016. Following is a summary of key studies to date.
The most clinically relevant outcome measures of ESWT are pain and functional limitations. Pain is a subjective, patient-reported measure. Therefore, pain outcomes require quantifiable pre- and post-treatment measures. Pain is most commonly measured with a visual analogue scale (VAS). Quantifiable pre- and post-treatment measures of functional status are also used, such as SF 12 and SF 36. Minor adverse effects of ESWT are common but transient, including local pain, discomfort, local trauma, bleeding, and swelling. More serious adverse outcomes of ESWT may potentially include neurologic damage causing numbness or tingling, permanent vascular damage, or rupture of a tendon or other soft tissue structure.

Because of the variable natural history of plantar fasciitis and the subjective nature of the outcome measures, randomized controlled trials (RCTs) are needed to determine whether outcomes are improved with ESWT. Trials should include a homogenous population of patients with a defined clinical condition, use standardized outcome measures whenever possible, and define \textit{a priori} the magnitude of response that is clinically significant.

**ESWT for Plantar Fasciitis**

**Systematic Reviews**

Eight studies met the inclusion criteria for the TEC 2004 Assessment. Five double-blind RCTs, reporting on 992 patients, were considered to be of high quality. Overall, evidence included in the 2004 TEC Assessment showed a statistically significant effect on between-group difference in morning pain measured on a 0–10 VAS score. Uncertain was the clinical significance of the change. The absolute value and effect size were small. The most complete information on the number needed to treat (NNT) to achieve 50–60% reduction in morning pain was from 2 studies of high-energy ESWT (and including confidential data provided by Dornier), combined NNT = 7 (95% confidence interval [CI]: 4–15). Improvements in pain measures were not clearly associated with improvements in function. Effect size for improvement in pain with activity was nonsignificant, based on reporting for 81% of patients in all studies and 73% of patients in high-energy ESWT studies. Success in improvement in Roles and Maudsley (RM) score was reported for fewer than half the patients: although statistically significant, CIs were wide. Where reported, improvement in morning pain was not accompanied by significant difference in quality-of-life measurement (SF-12, physical and mental scales) or use in pain medication.

Meta-analyses of RCTs published since the 2004 TEC Assessment have reported that ESWT for plantar fasciitis is better than or comparable to placebo in reducing pain and improving functional status in the short-term. However, studies evaluated in these meta-analyses are subject to a number of limitations. Individual RCTs selected reported inconsistent results and heterogeneity in the studies sometimes precluded meta-analysis of pooled data. Outcomes measured and study protocols (eg, dose intensities, type of shockwaves, frequency of treatments) also often lacked uniformity. Additionally, given that plantar fasciitis often resolves within a 6-month period, longer follow-up studies are needed to compare ESWT results with the natural resolution of the condition. The clinical significance of results reported at shorter follow-up, such as 3 months, is uncertain.

In a 2014 systematic review and meta-analysis with more restrictive inclusion criteria, Yin et al evaluated 7 RCTs or quasi-RCTs of ESWT for chronic (at least 6 months) recalcitrant plantar fasciitis. For the primary outcome of treatment success rate, which was defined differently across the included studies, pooled
analysis of the 5 trials (N=448 subjects) that evaluated low-intensity ESWT showed that ESWT was more likely than control to lead to treatment success (pooled risk ratio [RR], 1.69; 95% CI, 1.37 to 2.07; p<0.001).

In pooled analysis of the 2 trials (N=105 subjects) that evaluated high-intensity ESWT, there was no difference between ESWT and control in treatment success. A strength of this analysis is restricting the population to patients with at least 6 months of symptoms, because this is a clinical population that is more difficult to treat and less likely to respond to interventions. However, a weakness of this study is the heterogeneity in the definition of “treatment success,” which makes interpreting the pooled analysis challenging.

**Randomized Controlled Trials**

In 2015, Gollwitzer et al reported results of a sham-controlled RCT, with patients and outcome assessments blinded, evaluating ESWT for plantar fasciitis present for at least 6 months and refractory to at least 2 nonpharmacologic and 2 pharmacologic treatments. A total of 250 subjects were enrolled and treated (126 in the ESWT group, 124 in the placebo group). For the study’s primary outcome, overall reduction of heel pain, measured by percentage change of the VAS composite score 12 weeks after the last intervention compared with baseline, the median decrease was greater for the ESWT group (-69.2%) than for the placebo group (-34.5%; Mann-Whitney effect size, 0.6026; p=0.003). Secondary outcomes included success rates (defined as decrease of heel pain of at least 60% from baseline for at least 2 of 3 heel pain VAS measurements) for a variety of heel pain measurements. Secondary outcomes generally favored ESWT group. For example, 54.4% of ESWT patients had reduced overall heel pain compared with 37.2% of placebo patients (odds ratio [OR], 2.015; p=0.004, 1-sided). Most patients reported satisfaction with the procedure. Strengths of this study included intention-to-treat analysis, use of validated outcome measures, and at least some reporting of changes in success rates (rather than percent decrease in pain) for groups. There was some potential for bias because treating physicians were unblinded.

Some of the representative RCTs trials included in the systematic reviews previously described are as follows:

In 2005, results were reported from FDA-regulated trials delivering ESWT with the Orthospec, and Orbasone Pain Relief System. In the RCT used to support the FDA-approval of Orthospec, investigators conducted a multicenter, double-blind, sham-controlled trial that randomized 172 participants with chronic proximal plantar fasciitis failing conservative therapy to ESWT or sham treatments in a 2 to 1 ratio. At 3 months, the ESWT arm had less investigator-assessed pain with application of a pressure sensor (0.94 points lower on a 10-point VAS; 95% CI, 0.02 to 1.87). However, there was no difference in improvement in patient-assessed activity and function between ESWT and sham groups. In the RCT used to support the FDA-approval of Orbasone, investigators conducted a multicenter, randomized, sham-controlled, double-blind trial in which 179 participants with chronic proximal plantar fasciitis were randomized to active or sham treatment. At 3 months, both active and sham groups improved in patient-assessed pain on awakening (by 4.6 and 2.3 points, respectively, on a 10-point VAS; crude difference between groups at 3 months of 2.3; 95% CI, 1.5 to 3.3). While ESWT was associated with more rapid improvement (and statistically significant) in a mixed-effects regression model, insufficient details were provided to evaluate the analyses.
Gerdesmeyer et al. reported a multicenter double-blind RCT of rESWT conducted for FDA PMA of the Dolorclast from EMS Electro Medical Systems in 2008. In this study, 252 patients were randomized, 129 to rESWT and 122 to sham treatment. The patients had heel pain for at least 6 months and failure of at least 2 nonpharmacologic and 2 pharmacologic treatments prior to entry into the study. Three treatments at weekly intervals were planned, and more than 90% of patients in each group had all 3 treatments. Outcome measures were composite heel pain (pain on first steps of the day, with activity and as measured with Dolormeter), change in individual VAS scores, and RM score measured at 12 weeks and 12 months. Success was defined as at least 60% improvement in 2 of 3 VAS scores or, if less pain reduction, then the patient had to be able to work and complete activities of daily living, had to be satisfied with the outcome of the treatment, and must not have required any other treatment to control heel pain. Secondary outcomes at 12 weeks included changes in RM score, SF-36 physical score component percent changes, SF-36 Mental Component Summary score percent changes, investigator's judgment of effectiveness, patient's judgment of therapy and patient recommendation of therapy to a friend. At the 12-week follow-up, radial ESWT was followed by a decrease of the composite VAS score of heel pain by 72.1% versus 44.7% after placebo (p=0.022). The success rate for the composite score was 61% versus 42% (p=0.002). Statistically significant differences were noted on all secondary measures. A number of limitations prevent definite conclusions from being reached, including the following: the limited data concerning specific outcomes (eg, presenting percent changes rather than actual results of measures); inadequate description of prior treatment (or intensity of treatment) provided before referral to the study; use of the composite outcome measure; and no data on the use of rescue medication. In addition, the clinical significance of changes (and relative changes) in outcome measures is uncertain.

Several smaller trials (50 patients or less) show inconsistent results.

One RCT compared ESWT to an active alternative, endoscopic plantar fasciotomy. This study included 65 patients with refractory plantar fasciitis who had failed at least 3 lines of treatment in the preceding 6 months. Outcome measures were a 0-100 VAS of morning pain, the American Orthopaedic Foot and Ankle-Hindfoot scale (AOFAS), and patient subjective assessment using the 4-item RM score. Over the course of 1-year follow-up, both groups improved significantly on each outcome parameter, and there were no significant differences between groups. The percent of patients achieving a least a 50% reduction in the AOFAS score was reported in 74% (25/34) of patients in the ESWT group compared to 68% (21/31) patients in the surgery group (p = 0.79). Success rates at 1 year, defined as a patient-reported good or excellent outcome per the RM score, was reached in 70.6% (24/34) patients in the ESWT group compared to 77.4% (24/31) in the surgery group. At 2 years of follow-up, the percent reporting success was higher in the surgery group, with 80% (20/25) reporting a successful outcome versus 50% (13/26, p = 0.03) in the ESWT group. Similarly, at 3 years’ follow-up, the percent reporting success was 80% (20/25) in the surgery group compared to 48% (11/23) in the ESWT group (p = 0.021). Nonrandomized studies have also reported outcomes after ESWT for plantar fasciitis, but given the availability of randomized trials, these studies do not provide additional evidence about ESWT’s efficacy compared with alternatives.
Section Summary

There are numerous RCTs, including several well-designed double-blinded RCTs, that evaluate ESWT for treatment of plantar fasciitis. The evidence is mixed, with some studies reporting a benefit and others not reporting a benefit. The reasons for this variability in the literature are not clear. In studies that report a benefit, the magnitude of effect on some or all of the outcomes is of uncertain clinical significance. Definitive, clinically meaningful treatment benefits at 3 months are not apparent, nor is it evident that the longer term disease natural history is altered with ESWT. As a result, it is not possible to conclude that ESWT improves outcomes for patients with plantar fasciitis.

Tendinitis of the Elbow (Epicondylitis)

Systematic Reviews

Six randomized, double-blinded, placebo-controlled trials enrolling 808 patients with lateral epicondylitis met the inclusion criteria for the 2004 TEC Assessment. Four trials were rated “good” quality and are summarized below. Three trials utilized low-energy ESWT and one used high-energy ESWT. Two trials reported positive effects on pain, one trial had mixed results, and another large sham-controlled study reported negative results with ESWT.

- In the SONOCUR trial, 114 patients were randomized to low-energy ESWT or sham ESWT for 3 treatment sessions administered in 1-week intervals. The main outcome measures were percent response on self-reported pain scale (at least 50% improvement on 0–100 VAS) and change in the Upper Extremity Function Scale (UEFS). Results of the 2 main outcome measures at 3 months showed greater improvement in the ESWT group. Response rate was 60% in the active treatment group and 29% in the placebo group (p < 0.001). There was a 51% improvement in the UEFS score for the active treatment group, compared with a 30% improvement in the placebo group (p < 0.05).

- The Rompe et al. trial randomized 78 tennis players to 3 treatments at week intervals of low-energy or sham ESWT. Outcomes included pain ratings during wrist extension and the Thomsen Provocation Test, the RM score, the UEFS score, grip strength, and satisfaction with return to activities. At 3 months’ follow-up, the ESWT group, compared to placebo, significantly improved on all outcomes except grip strength. Treatment success (at least a 50% decrease in pain) was 65% for the ESWT group and 28% for the placebo group (p < 0.01) and 65% of the ESWT group, compared to 35% of the placebo group, were satisfied with their return to activities (p = 0.01).

- The OssaTron trial randomized 183 patients to a single session of high-energy or sham ESWT. Treatment success was defined as achieving an RM score of 1 or 2 with no additional treatments. At the 8-week follow-up, the ESWT group had a greater rate of treatment success than the placebo group (35% vs. 22%, respectively p < 0.05). Mainly responsible for group differences in treatment success was the investigator assessment of pain (48% vs. 29%, respectively p < 0.01); the improvements in self-assessment of pain (81% vs. 70%, respectively; p = 0.06) and non-use of pain medication (81% vs. 70%, respectively; p = 0.09) were only marginal.

- In the Haake et al. trial, 272 patients were randomized to 3 sessions of low-energy or sham ESWT. Treatment success was defined as achieving an RM score of 1 or 2 with no additional treatments. At 12 weeks, the ESWT success rate was 25.8%, and the placebo success rate was 25.4%. The percentage of RM scores below 3 did not differ between groups at either 12 weeks (31.7% ESWT
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vs. 33.1% placebo) or at 1 year (65.7% ESWT vs. 65.3% placebo) of follow-up. Furthermore, the groups did not differ along any of 5 pain assessment measures or on grip strength.

Other systematic reviews published since the 2004 TEC Assessment have come to similar conclusions. A 2005 Cochrane review concluded “there is ‘Platinum’ level evidence [the strongest level of evidence] that shock wave therapy provides little or no benefit in terms of pain and function in lateral elbow pain.” A 2013 systematic review of electrophysical therapies for epicondylitis concluded that the evidence is conflicting on the short-term benefits of ESWT. No evidence was found demonstrating any long-term benefits with ESWT over placebo for epicondylitis treatment.

Randomized Controlled Trials
Several RCTs on ESWT for lateral epicondylitis have been published since the 2004 TEC Assessment. In 2005, Pettrone and McCall reported results from a double-blind randomized trial conducted in 3 large orthopedic practices for 114 patients receiving either ESWT in a “focused” manner (2000 impulses at 0.06 mJ/mm² without local anesthesia) weekly for 3 weeks or placebo. Randomization was maintained through 12 weeks, and benefit demonstrated with respect to a number of outcomes: pain, functional scale, and activity score. Pain assessed on the VAS (scaled here to 10 points) declined at 12 weeks in the treated group from 7.4 to 3.8; among placebo patients from 7.6 to 5.1. A reduction in Thomsen test pain of at least 50% was demonstrated in 60.7% of those treated compared with 29.3% in the placebo group. Mean improvement on a 10-point UEFS activity score was 2.4 for ESWT-treated patients compared with 1.4 in the placebo group—difference at 12 weeks of 0.9 (95% CI, 0.18 to 1.6). Although this study found benefit of ESWT for lateral epicondylitis over 12 weeks, the placebo group also improved significantly; whether the natural history of disease was altered is unclear.

In 2008, Staples and colleagues reported a double-blind controlled trial of ultrasound-guided ESWT for epicondylitis in 68 patients. Patients were randomized to receive 3 ESWT treatments or 3 treatments at a subtherapeutic dose at weekly intervals. There were significant improvements in most of the 7 outcome measures for both groups over 6 months of follow-up and no between-group differences. The authors found little evidence to support use of ESWT for this indication.

At least 2 RCTs have compared ESWT with active comparators. Gunduz et al compared ESWT with 2 active comparators. This trial randomized 59 patients with lateral epicondylitis to ESWT, physical therapy, or a single corticosteroid injection. Outcome measures were a VAS for pain, grip strength and pinch strength by dynamometer, and ultrasound. The authors reported that VAS pain scores improved significantly in all 3 groups at 6-month follow-up, but no between-group differences were recorded. No consistent changes were reported for grip strength or on ultrasonography. Lizis compared ESWT with therapeutic ultrasound among 50 patients with chronic tennis elbow. For most pain measures assessed, pain was lower in the ESWT group immediately posttreatment and at 3 months, with the exception of pain on gripping, which was higher in the ESWT group. While trial results favored ESWT, there was a high risk of bias due to a number of factors, particularly lack of blinding of participants and outcome assessors, which make interpretation of results difficult.
A small RCT comparing radial ESWT (n=28) or sham radial ESWT (n=28) for lateral epicondylitis did not find significant differences between groups in grip strength or function. However, this trial may have been underpowered to detect a difference.

Nonrandomized observational studies have reported functional outcomes after ESWT for epicondylitis; however, these studies provided limited evidence about the comparative effectiveness of ESWT for lateral epicondylitis compared with other therapies

**Section Summary**

The most direct evidence related to the use of ESWT to treat lateral epicondylitis comes from multiple small RCTs, which have not consistently shown outcome improvements beyond those seen in control groups with ESWT. The highest quality trials have tended to show no benefit, and systematic reviews have generally concluded that the evidence does not support a treatment benefit.

**ESWT for Shoulder Tendinopathy**

Numerous small RCTs have evaluated ESWT for shoulder tendinopathy, primarily calcific and noncalcific tendinopathy of the rotator cuff. In a 2015 systematic review of various passive physical modalities for shoulder pain, which included 11 studies considered to be at low risk of bias, 5 studies reported on ESWT. Three, published from 2003 to 2011, were for calcific shoulder tendinopathy, including 1 RCT comparing high-energy ESWT with low-energy ESWT (N=80), 1 RCT comparing radial ESWT with sham ESWT (N=90), and 1 RCT comparing high-energy ESWT with low-energy ESWT and sham ESWT (N=144). All 3 trials reported statistically significant differences between groups for change in VAS score for shoulder pain.

In a 2013 systematic review and meta-analysis, Ioppolo et al included 6 RCTs on ESWT compared with sham treatment or placebo for calcific shoulder tendinopathy. Greater shoulder function and pain improvements were found at 6 months with ESWT over placebo. Most studies were considered to be low quality. Huisstede et al published a systematic review of RCTs in 2011 that included 17 RCTs of calcific (n=11) and noncalcific (n=6) tendinopathy of the rotator cuff. Moderate-quality evidence was found for the efficacy of ESWT versus placebo for calcific tendinopathy, but not for noncalcific tendinopathy. High-frequency ESWT was found to be more efficacious than low-frequency ESWT for calcific tendinopathy.

In 2014, Bannuru et al published a systematic review of RCTs comparing high-energy ESWT with placebo or low-energy ESWT for the treatment of calcific or noncalcific shoulder tendinitis. In 7 studies comparing ESWT with placebo for calcific tendinitis, all studies reported significant improvements in pain or functional outcomes associated with ESWT. Only high-energy ESWT was consistently associated with significant improvements in both pain and functional outcomes. In 8 studies comparing high- with low-energy ESWT for calcific tendinitis, studies did not demonstrate significant improvements in pain outcomes, although shoulder function was improved with high-energy ESWT. Trials were reported to be generally of low quality with a high risk of bias.

In another 2014 systematic review of RCTs comparing high-energy ESWT with low-energy ESWT, Verstraelen et al evaluated 5 studies including a total of 359 patients with calcific shoulder tendinitis. Three
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studies were considered high quality. High-energy ESWT was associated with significant improvements in functional outcomes with a mean difference at 3 months of 9.88 (95% CI, 0.04 to 10.72; p<0.001). High-energy ESWT was more likely to lead to resolution of calcium deposits at 3 months (pooled odds ration [OR], 3.4 [95% CI, 1.35 to 8.58, p=0.009]). Pooled analysis could not be performed for 6-month follow-up data.

Kim et al compared ultrasound-guided needling combined with subacromial corticosteroid injection to ESWT in patients with unilateral calcific shoulder tendinopathy and ultrasound-documented calcifications of the supraspinatus tendon. Sixty-two patients were enrolled and randomized to ESWT or needling/steroid injection. Fifty-four patients were included in the data analysis (8 subjects were lost to follow-up). ESWT was performed for 3 sessions once weekly. Radiologic evaluation was blinded, although it was not specified whether evaluators for pain and functional outcomes were blinded. After an average follow-up of 23.0 months (range, 12.1-28.5 months), functional outcomes improved in both groups: for the ultrasound-guided needling group, scores on the American Shoulder and Elbow Surgeons (ASES) scale improved from 41.5 to 91.1 (p=0.001) and on the Simple Shoulder Test (SST) improved from 38.2% to 91.7% (p=0.03). In the ESWT group, scores on the ASES scale improved from 49.9 to 78.3 (p=0.026) and on the SST from 34.0% to 78.6% (p=0.017). Similarly, VAS pain scores improved from baseline to last follow-up in both groups (6.8-1.1 for ultrasound-guided needling [p=0.006], 6.3-2.4 for ESWT [p=0.026]). At the last follow-up visit, calcium deposit size was smaller in the US-needling group (0.5 mm) than in the ESWT group (5.6 mm; p=0.001).

An example of a high-energy versus low-energy trial is that by Schofer et al, which assessed 40 patients with rotator cuff tendinopathy. An increase in function and reduction of pain were found in both groups (p<0.001). Although improvement in Constant score were greater in the high-energy group, there were no statistically significant differences in any outcomes studied (Constant score, pain, subjective improvement) at 12 weeks or 1 year posttreatment.

At least 1 RCT has evaluated patients with bicipital tendinitis of the shoulder. This trial randomized 79 patients with tenosynovitis to ESWT or sham treatment. ESWT was given for 4 sessions over 4 weeks. Outcomes were measured at up to 12 months by a VAS for pain and the L'Insalata Shoulder Questionnaire. The mean decrease in the VAS score at 12 months was greater for the ESWT group (4.24 units) compared with sham (0.47 units; p<0.001). There were similar improvements in the L'Insalata Shoulder Questionnaire, with an improvement in scores for the ESWT group of 22.8 points.

Section Summary
A number of small RCTs have evaluated the use of ESWT to treat shoulder tendinopathy, which have been summarized in several systematic reviews and meta-analyses. Although some trials have reported a benefit in terms of pain and functional outcomes, particularly for high-energy ESWT for calcific tendinopathy, many available trials have been considered poor quality. Further high-quality trials are needed to determine whether ESWT improves outcomes for shoulder tendinopathy.
ESWT for Achilles Tendinopathy
Al-Abbad and Simon reported on a systematic review of 6 studies on ESWT for Achilles tendinopathy. Included in the review were 4 small RCTs and 2 cohort studies. Satisfactory evidence was found demonstrating ESWT effectiveness in the treatment of Achilles tendinopathy at 3 months in 4 studies. However, 2 of the RCTs reviewed found no significant difference between ESWT and placebo in the treatment of Achilles tendinopathy.

In 2015, Mani-Babu et al reported results of a systematic review of studies evaluating ESWT for lower-limb tendinopathies, including Achilles tendinopathy, patellar tendinopathy, and greater trochanteric pain syndrome. The review included 20 studies, 11 of which evaluated ESWT for Achilles tendinopathy, including 5 RCTs, 4 cohort studies, and 2 case-control studies. In pooled analysis, the authors reported that ESWT was associated with greater short-term (<12 months) and long-term (>12 months) improvements in pain and function compared with nonoperative treatments, including rest, footwear modifications, anti-inflammatory medication, and gastrocnemius-soleus stretching and strengthening. The authors noted that findings from RCTs of ESWT for Achilles tendinopathy were contradictory, but that there was some evidence for short-term improvements in function with ESWT.

Costa and colleagues reported a randomized, double-blind, placebo-controlled trial of ESWT for chronic Achilles tendon pain treated monthly for 3 months in 2005. The study randomized 49 participants and was powered to detect a 50% reduction in VAS pain scores. No difference in pain relief at rest or during sport participation was found at 1 year. Two older ESWT-treated participants experienced tendon ruptures.

In 2008, Rasmussen et al reported a single-center double-blind controlled trial with 48 patients, half of them randomized after 4 weeks of conservative treatment to 4 sessions of active rESWT and half to sham ESWT. The primary end point was AOFAS score measuring function, pain, and alignment and pain on VAS. The AOFAS score after treatment increased from 70 to 88 in the ESWT group and from 74 to 81 in the control (p=0.05). Pain was reduced in both groups with no statistically significant difference between groups. The authors noted that the AOFAS score may not be appropriate for the evaluation of treatment of Achilles tendinopathy.

ESWT for Patellar Tendinopathy
Van Leeuwen et al conducted a literature review to study the effectiveness of ESWT for patellar tendinopathy and to draft a treatment protocol which included a review of 7 articles. The authors found that most studies had methodologic deficiencies, small numbers and/or short follow-up periods, and treatment parameters varied among studies. They concluded that ESWT appears to be safe and promising treatment but that a treatment protocol cannot be recommended and further basic and clinical research is required. In an RCT of patients with chronic patellar tendinopathy (N=46), despite at least 12 weeks of nonsurgical management, improvements in pain and functional outcomes were significantly greater (p<0.05) with plasma-rich protein injections than ESWT at 6 and 12 months, respectively.

In the 2015 systematic review of ESWT for lower-extremity tendinopathies (previously described), Mani-Babu et al identified 7 studies of ESWT for patellar tendinopathy, including 2 RCTs, 1 quasi-RCT, 1 retrospective cross-sectional study, 2 prospective cohort studies, and 1 case-control study. The 2 RCTs
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came to different conclusions: 1 RCT found no difference in outcomes between ESWT and placebo at 1, 12, or 22 weeks, whereas an earlier RCT found improved outcomes on vertical jump test and Victorian Institute of Sport Assessment Questionnaire–Patellar scores at 12 weeks with ESWT compared with placebo. Two studies that evaluated outcomes beyond 24 months found ESWT comparable to patellar tenotomy surgery and better than nonoperative treatments.

ESWT Medial Tibial Stress Syndrome
In 2010, Rompe and colleagues published a report on the use of ESWT in medial tibial stress syndrome (MTSS), commonly known as “shin splints”. In this non-randomized cohort study, 47 patients with MTSS for at least 6 months received 3 weekly sessions of rESWT and were compared to 47 age-matched controls at 4 months. Mild adverse events were noted in 10 patients: skin reddening in 2 patients and pain during the procedure in 8 patients. Patients rated their condition on a 6-point Likert scale. Successful treatment was defined as self-rating “completely recovered” or “much improved”. The authors reported a significant success rate of 64% (30/47) in the treatment group compared to 30% (14/47) in the control group. This study represents another potential use for ESWT. In a letter to the editor, Barnes raised several limitations of this nonrandomized study, including the possibility of selection bias. Larger, randomized trials are needed.

ESWT for Osteonecrosis of the Femoral Head
A systematic review of ESWT in osteonecrosis (avascular necrosis) of the femoral head was conducted by Alves and colleagues in 2009. Only five articles, all from non-US sites, were identified: two RCTs, one comparative study, one open-label study, and one case report for a total of 133 patients. Several studies were from one center in Taiwan. Of the two RCTs, one (n = 48) was randomized to the use of concomitant alendronate; ESWT treatments were in both arms of the study and ESWT was therefore not the comparator. The other RCT compared ESWT to a standard surgical procedure. All results noted a reduction in pain over the time of the study, which was attributed by each study’s authors to a positive effect of ESWT. However, the authors of this review noted the limitations of the available evidence: lack of double-blind design, small numbers of patients included, short duration of follow-up, and non-standard intervention, e.g., energy level and number of treatments.

A comparative study not included in the Alves et al. systematic review was published by Chen and colleagues in 2009. In this small study, for each of 17 patients with bilateral hip osteonecrosis one side was treated with total hip arthroplasty, while the other was treated with ESWT. Each patient was evaluated at baseline and after treatment utilizing VAS for pain and Harris hip score, a composite measure of pain and hip function. There was a significant reduction in scores before and after treatment in both treatment groups. Hips treated with ESWT were also evaluated for radiographic reduction of bone marrow edema on magnetic resonance imaging (MRI), which also appeared to be reduced. The authors then compared the ESWT-treated data to the total hip arthroplasty results, stating that the magnitude of improvement was greater for the ESWT-treated hips. However, hips were not randomized to treatment intervention; the side with the greater degree of disease was treated with surgery in each case. Moreover, time between hip interventions within the same patient averaged 17.3 months, with a range of 6 to 36 months; in all but one case, surgery preceded ESWT. Therefore, conclusions about the superiority of one intervention over the other cannot be made.
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Section Summary
A limited body of evidence addresses ESWT for osteonecrosis of the femoral head, including 2 small RCTs. The available evidence is insufficient to allow conclusions about the efficacy of ESWT for osteonecrosis.

ESWT for Nonunion, Delayed Union, Acute Fractures
In 2010, Zelle and colleagues reviewed the English and German medical literature for studies of ESWT in the treatment of fractures and delayed union/nonunion, restricted to studies with greater than 10 patients. Ten case series and one RCT were identified. Number of treatment sessions, energy protocols, and definitions of nonunion varied across studies; union rate after intervention was likewise heterogeneous, ranging from 40.7% to 87.5%. The authors conclude the overall quality of evidence is conflicting and of poor quality.

The RCT included in the Zelle review reported on the use of ESWT in acute long bone fractures. Wang and colleagues randomized trauma patients (n = 56) with femur or tibia fractures to a single ESWT treatment following surgical fixation while still under anesthesia. Patients in the control group underwent surgical fixation but did not receive the ESWT treatment. Patients were evaluated for pain and percent weight-bearing capability on the affected leg by an independent, blinded evaluator. Radiographs taken at these same intervals were evaluated by a radiologist blinded to study group for fracture healing or nonunion. Both groups showed significant improvement in pain scores and weight-bearing status. Between-group comparisons of pain by VAS and weight bearing favored study patients at each interval. At six months, patients who had received ESWT had VAS scores of 1.19 compared to 2.47 in the control group (p < 0.001); mean percentage of weight bearing at six months was 87% versus 78%, respectively (p = 0.01). Radiographic evidence of union at each interval also favored the study group. At 6 months, 63% (17/27) of the study group achieved fracture union compared to 20% (6/30) in the control group (p < 0.001). The authors note some limitations to the study: the small number of patients in the study, surgeries performed by multiple surgeons and questions regarding adequacy of randomization.

One RCT of ESWT compared to surgery for nonunion of long bone fractures was identified. Cacchio and colleagues enrolled 126 patients into 3 groups: low- or high-energy ESWT therapy, or surgery. Patients were identified for participation in the study if referred to one of 3 Italian centers with nonunion fractures, here defined as at least 6 months without evidence of radiographic healing. The primary endpoint was radiographic evidence of healing. Secondary endpoint data of pain and functional status were collected by blinded evaluators. Neither patients nor treating physicians were blinded. At 6 months, rates in the lower energy ESWT, higher energy ESWT, and surgical arms had similar healing rates (70%, 71%, and 73%, respectively). There was no significant difference among the groups at this stage. All groups’ healing rates improved at further follow-up at 12 and 24 months without significant between-group differences. Secondary endpoints of pain and disability were also examined and were similar. The authors believe this to be the first RCT of its kind and encourage additional study. Lack of blinding may have led to differing levels of participation in other aspects of the treatment protocol.

Section Summary
The evidence related to the use of ESWT for the treatment of fractures or for fracture nonunion or delayed union includes several relatively small RCTs with methodologic issues noted, along with case series. The
available evidence is insufficient to allow conclusions about the efficacy of ESWT in fracture nonunion, delayed union, and acute long bone fractures.

ESWT for Spasticity

Systematic Reviews

Lee et al conducted a meta-analysis of studies evaluating ESWT for patients with spasticity secondary to a brain injury. Studies included evaluated ESWT as sole therapy and reported pre- and post-intervention Modified Ashworth Scale (MAS) scores. Five studies were selected, 4 examining spasticity in the ankle plantar flexor and 1 examining spasticity in the wrist and finger flexors; 3 studies evaluated post-stroke spasticity and 2 evaluated spasticity associated with cerebral palsy. Immediately post-ESWT, MAS scores improved significantly compared with baseline (standardized mean difference [SMD], -0.792; 95% CI, -1.001 to -0.583; p<0.001). After 4 weeks post-ESWT, MAS scores continued to demonstrate significant improvements compared with baseline (SMD, -0.735; 95% CI, -0.951 to -0.519; p<0.001). A strength of this meta-analysis was its use a consistent and well-definable outcome measure. However, the MAS does not account for certain clinically important factors related to spasticity, including pain and functional impairment.

Randomized Controlled Trials

The efficacy and safety of radial ESWT in the treatment of spasticity in patients with cerebral palsy was examined in a small European RCT in 2011. The 15 patients in this trial were divided into 3 groups (ESWT in a spastic muscle, ESWT in both spastic and antagonistic muscle, placebo ESWT) and treated in 3 weekly sessions. Spasticity was evaluated in the lower limbs by passive range of motion with a goniometer and in the upper limbs with the Ashworth Scale (0 [not spasticity] to 4 [severe spasticity]) at 1, 2, and 3 months posttreatment. Blinded evaluation showed significant differences between the ESWT and placebo groups for range of motion and Ashworth Scale score. For the group in which only the spastic muscle was treated, there was a 1-point improvement on the Ashworth Scale (p=0.05 vs placebo); for the group in with both muscles treated, there was a 0.5-point improvement (p=NS vs placebo); and for the placebo group, there was no change. The significant improvements were maintained at 2 months posttreatment, but not at 3 months.

Noncomparative Studies

Daliri et al evaluated the efficacy of a single session of ESWT for treatment of post-stroke wrist flexor spasticity in a single-blinded trial in which each patient received sham control and active stimulation. Fifteen patients at a mean 30 months post-stroke were included, each of whom received 1 sham stimulation followed 1 week later by 1 active ESWT treatment. Investigators were not blinded. Outcomes evaluated included MAS score to evaluate spasticity intensity, the Brunnstrom Recovery Stage tool to assess motor recovery, and the neurophysiological measure of Hmax/Mmax to measure alpha motoneuron excitability. MAS scores and Brunnstrom Recovery Stage scores did not improve after sham treatment. MAS scores improved significantly from baseline (mean, 3) to post active treatment (mean scores, 2, 2, and 2 immediately posttheraphy, 1 week posttherapy, and 5 weeks posttherapy, respectively; p<0.05). Hmax/Mmax ratio improved from 2.30 before therapy to 1 the week after active ESWT (p=0.047). Brunnstrom scores did not significantly improve after active ESWT. Given the lack of a control group, this study provides limited evidence about the comparative efficacy of ESWT for post-stroke spasticity.
Santamato et al evaluated outcomes after a single session of ESWT for post-stroke plantar flexor spasticity (equinus foot) in 23 subjects. Subjects with gastrocnemius/soleus Heckmann scores on ultrasound from I to III (maximum score, IV, which corresponds to very high muscle echo intensity due to fat and fibrosis) had significant improvements in MAS scores from baseline to immediately post-ESWT (3.5 to 2.1, p<0.01) and from baseline to 30 days post-ESWT (3.5 to 2.6, p<0.05). Those with a Heckmann score of IV showed improvements in MAS scores from baseline to immediately post-ESWT (4.7 to 3.3, p<0.05), but 30-day scores did not differ significantly from baseline. Results were similar for passive ankle dorsiflexion scores.

**Section Summary: ESWT for Spasticity**

A relatively small body of evidence, with limited RCT evidence, is available on the use of ESWT for spasticity. Several studies have demonstrated improvements in spasticity measures after ESWT. More controlled trials are needed to determine whether ESWT leads to clinically meaningful improvements in pain and/or functional outcomes for spasticity.

**ESWT for Other Conditions**

ESWT has been investigated in small studies for other conditions, including coccydynia in a case series of 2 patients and painful neuromas at amputation sites in a small RCT including 30 subjects.

In the 2015 systematic review of ESWT for lower extremity tendinopathies by Mani-Babu et al the authors reviewed 2 studies of ESWT for greater trochanteric pain syndrome, including 1 quasi-RCT comparing ESWT with home therapy or corticosteroid injection and 1 case-control study comparing ESWT with placebo. ESWT was associated with some benefits compared with placebo or home therapy.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 3.

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NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.

**Summary**

For individuals who have plantar fasciitis who receive ESWT, the evidence includes numerous RCTs, including several well-designed, double-blinded RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The available RCTs have demonstrated mixed findings, with some studies reporting a benefit and others reporting no benefit. Where statistically significant differences have been reported, the magnitude of effect for some outcomes is of
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uncertain clinical significance. The most recent RCT evaluating ESWT for plantar fasciitis was fairly well designed, well conducted, and showed some reductions in pain with ESWT; additional confirmatory trials are needed to permit more certainty about the effects of ESWT. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have lateral epicondylitis, shoulder tendinopathy, Achilles tendinopathy, or patellar tendinopathy who receive ESWT, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The available RCTs for these tendinopathies have methodologic limitations. 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 tendinopathies. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have medial tibial stress syndrome, osteonecrosis of the femoral head, and acute fractures and delayed fracture union who receive ESWT, the evidence includes RCTs and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The available comparative evidence is limited, and does not permit conclusions about the benefits of ESWT relative to alternatives. 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 short-term improvements in Modified Ashworth Scale scores, but direct evidence on the effect of ESWT on more clinically meaningful measures (eg, 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 from results of multiple studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

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15. Greve JM, Grecco MV, Santos-Silva PR. Comparison of radial shockwaves and conventional physiotherapy for treating plantar fasciitis. Clinics (Sao Paulo) 2009; 64(2):97-103.


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Policy History
Original Effective Date: 08/27/2001
Current Effective Date: 03/15/2017
08/16/2001 Medical Policy Committee review
08/27/2001 Managed Care Advisory Council approval
03/21/2002 Medical Policy Committee review. Coverage eligibility changed to reflect current literature.
03/25/2002 Managed Care Advisory Council approval
02/03/2004 Medical Director Review
02/17/2004 Medical Policy Committee review. Format revision. Coverage eligibility change to reflect the investigational status of the technology identified in current literature.
02/23/2004 Managed Care Advisory Council approval. Claims Processing effective date based on revised policy will be 4/1/04.
02/01/2006 Medical Director review
02/15/2006 Medical Policy Committee approval. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
02/23/2006 Quality Care Advisory Council approval
02/13/2008 Medical Director review
02/20/2008 Medical Policy Committee approval. No change to coverage eligibility.
02/04/2009 Medical Director review
02/19/2009 Medical Policy Committee approval. No change to coverage eligibility.
02/04/2010 Medical Director review
02/17/2010 Medical Policy Committee approval. Title changed to Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions.
02/03/2011 Medical Policy Committee review
02/16/2011 Medical Policy Implementation Committee approval. No change to coverage statement.
02/02/2012 Medical Policy Committee review
02/15/2012 Medical Policy Implementation Committee approval. No change to coverage statement.
01/03/2013 Medical Policy Committee review
01/09/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/04/2013 Coding revised
01/09/2014 Medical Policy Committee review
01/15/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/05/2015 Medical Policy Committee review
03/20/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
03/04/2016 Medical Policy Committee review
03/16/2016 Medical Policy Implementation Committee approval. Added additional indications into coverage statement. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update
03/02/2017 Medical Policy Committee review
03/15/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 03/2018

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Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

Policy #  00039  
Original Effective Date:  08/27/2001  
Current Effective Date:  03/15/2017  

Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
   1. Consultation with the Blue Cross and Blue Shield Association TEC or other nonaffiliated technology evaluation center(s);
   2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. Reference to federal regulations.

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