Extracorporeal Shock Wave Therapy for Plantar Fasciitis and Other Musculoskeletal Conditions

Policy Number: 2.01.40       Last Review: 9/2016

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for Extracorporeal Shock Wave Therapy for Plantar Fasciitis and Other Musculoskeletal Conditions. This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
Extracorporeal shock wave therapy (ESWT), using either a high- or low-dose protocol or radial ESWT, is considered investigational, as a treatment of musculoskeletal conditions, including but not limited to plantar fasciitis; tendinopathies including tendinitis of the shoulder, tendinitis of the elbow (lateral epicondylitis), Achilles tendinitis, and patellar tendinitis; stress fractures, delayed union, non-union and avascular necrosis of the femoral head.

Considerations
Note: High-energy ESWT requires the use of anesthesia and is performed in a hospital or ambulatory surgery center. Low-energy ESWT is usually used in the office without anesthesia.

There are no specific CPT codes for the radial ESWT (rESWT). The existing category III CPT code for low energy ESWT - 0019T - should be used

Description of Procedure or Service

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<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
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<td>• With plantar fasciitis</td>
<td>• Extracorporeal shock wave therapy</td>
<td>• Conservative therapy (eg, stretching, heel supports)</td>
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<td>With lateral epicondylitis</td>
<td>Extracorporeal shock wave therapy</td>
<td>Conservative therapy (eg, physical therapy, rest) Nonsteroidal anti-inflammatory therapy</td>
<td>Symptoms, Functional outcomes, Quality of life, Medication use, Treatment-related morbidity</td>
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<td>Extracorporeal shock wave therapy</td>
<td>Conservative therapy (eg, physical therapy, rest) Nonsteroidal anti-inflammatory therapy</td>
<td>Symptoms, Functional outcomes, Quality of life, Medication use, Treatment-related morbidity</td>
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<td>With Achilles tendinopathy</td>
<td>Extracorporeal shock wave therapy</td>
<td>Conservative therapy (eg, heel lift, rest) Nonsteroidal anti-inflammatory therapy</td>
<td>Symptoms, Functional outcomes, Quality of life, Medication use, Treatment-related morbidity</td>
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<td>With patellar tendinopathy</td>
<td>Extracorporeal shock wave therapy</td>
<td>Conservative therapy (eg, icing, support) Nonsteroidal anti-inflammatory therapy</td>
<td>Symptoms, Functional outcomes, Quality of life, Medication use, Treatment-related morbidity</td>
</tr>
<tr>
<td>With medial tibial stress syndrome</td>
<td>Extracorporeal shock wave therapy</td>
<td>Conservative therapy (eg, icing, support)</td>
<td>Symptoms, Functional outcomes, Quality of life, Medication use, Treatment-related morbidity</td>
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<tr>
<td>With osteonecrosis of the femoral head</td>
<td>Extracorporeal shock wave therapy</td>
<td>Medication therapy (eg, alendronate) Hip arthroplasty</td>
<td>Symptoms, Functional outcomes, Quality of life, Medication use, Treatment-related morbidity</td>
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<td>Acute fracture nonunion or delayed union</td>
<td>Extracorporeal shock wave therapy</td>
<td>Surgical therapy</td>
<td>Symptoms, Functional outcomes, Quality of life, Medication use, Treatment-related morbidity</td>
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<tr>
<td>With spasticity</td>
<td>Extracorporeal shock wave therapy</td>
<td>Medication therapy</td>
<td>Symptoms, Functional outcomes</td>
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</table>
Extracorporeal shock wave therapy (ESWT) is a noninvasive method being evaluated 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. ESWT has been investigated for use in a variety of musculoskeletal conditions.

For individuals who have plantar fasciitis who receive ESWT, the evidence includes numerous randomized controlled trials (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 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.

**Background**

Extracorporeal shockwave treatment (ESWT), 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. Shock waves 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, such as 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 functions 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 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. It should be noted that 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>
</table>
| Lateral epicondylitis (elbow tendinitis/“tennis elbow”) | Lateral elbow (insertion of wrist extensors) | 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 | ▪ Rest  
▪ Activity modification  
▪ NSAIDs  
▪ Physical therapy  
▪ Orthotic devices | Corticosteroid injections; joint débridement (open or laparoscopic) |
| Shoulder tendinopathy                   | Rotator cuff muscle tendons, most commonly supraspinatus | Pain with overhead activity | ▪ Rest  
▪ Ice  
▪ NSAIDs  
▪ Physical therapy | Corticosteroid injections |
| Achilles tendinopathy                   | Achilles tendon                  | Pain or stiffness 2-6 cm above the posterior calcaneus | ▪ Avoidance of aggravating activities  
▪ Icing when symptomatic  
▪ NSAIDs  
▪ Heel lift | Surgical repair for tendon rupture |
| 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 | ▪ Icing  
▪ Supportive taping  
▪ Patellar tendon straps  
▪ NSAIDs | |

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 refers to a decelerating bone healing process, as identified in serial radiographs. (In contrast, nonunion serial radiographs show no evidence of
 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.

**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.

**Regulatory Status**

Currently, 6 extracorporeal shock wave therapy (ESWT) devices have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for orthopedic use; they are summarized in Table 2. FDA product code: NBN.

### 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>
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</thead>
<tbody>
<tr>
<td>OssaTron® device (HealthTronics, Marietta, GA)</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>
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<td></td>
<td></td>
<td></td>
<td>• Lateral epicondylitis</td>
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<tr>
<td>Epos™ Ultra (Dornier, Germering, Germany)</td>
<td>2002</td>
<td>Electromagnetic delivery system</td>
<td>Plantar fasciitis</td>
</tr>
<tr>
<td>Sonocur® Basic (Siemens, Erlangen, Germany)</td>
<td>2002</td>
<td>Electromagnetic delivery system</td>
<td>Chronic lateral epicondylitis (unresponsive to conservative therapy for &gt;6 mo)</td>
</tr>
<tr>
<td>Orthospec™ Orthopedic ESWT (Medispec, Germantown, MD)</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 (Orthometrix, White Plains, NY)</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, Switzerland)</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 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 (rESWT) received premarket 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.

**Rationale**

This evidence review was created in May 2001 based on a 2001 TEC Assessment that concluded that extracorporeal shock wave therapy (ESWT) met TEC criteria as a treatment for plantar fasciitis in patients who had not responded to conservative therapies.\(^1\) 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.\(^2\) 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.\(^3\),\(^4\) 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 used for musculoskeletal conditions are pain and functional limitations. Pain is a subjective, patient-reported measure. Therefore, pain outcomes require quantifiable pre- and posttreatment measures. Pain is most commonly measured with a visual analog scale (VAS). Quantifiable pre- and posttreatment measures of functional status are also used, such as 12-Item Short-Form Health Survey (SF-12) and SF-36. Minor adverse effects of ESWT are common but transient, including local pain, discomfort, trauma, bleeding, and swelling. More serious adverse events 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 other musculoskeletal conditions 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 a priori the magnitude of response that is clinically significant.
ESWT for Plantar Fasciitis

Systematic Reviews

Eight studies met the inclusion criteria for the 2004 TEC Assessment. Five double-blind RCTs, reporting on 992 patients, were considered to be of high quality. Overall, evidence included in this Assessment showed a statistically significant effect on between-group difference in morning pain measured on a 0-to-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% to 60% reduction in morning pain was from 2 studies of high-energy ESWT (and including confidential data provided by Dornier). The combined NNT was 7 (95% confidence interval [CI], 4 to 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, confidence intervals were wide. Where reported, improvement in morning pain was not accompanied by significant difference in quality-of-life measurement (SF-12 Physical and Mental Component Summary scores) 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 ESWT was more likely than control to lead to treatment success (pooled relative risk [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 clinical population more difficult to treat and less likely to respond to interventions. However, a weakness is the heterogeneity in the
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 discussed are as follows.

In 2005, results were reported from U.S. Food and Drug Administration (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 2:1 ratio. At 3 months, the ESWT arm had lower investigator-assessed pain levels with application of a pressure sensor (0.94 points lower on a 10-point VAS; 95% CI, 0.02 to 1.87). However, this improvement was not found for patient-assessed activity and function between groups. In the trial supporting the FDA approval of Orbasone™, investigators conducted a multicenter, randomized, sham-controlled, double-blind trial evaluating 179 participants with chronic proximal plantar fasciitis assigned to active or sham treatment. At 3 months, both active and sham groups improved in patient-assessed pain levels on awakening (by 4.6 and 2.3 points, respectively, on a 10-point VAS; absolute difference between groups at 3 months, 2.3; 95% CI, 1.5 to 3.3). While ESWT was associated with more rapid and statistically significant improvement in a mixed-effects regression model, insufficient details were provided to evaluate the analyses.

Gerdesmeyer et al reported on a multicenter double-blind RCT of radial ESWT conducted for FDA premarket approval of the Dolorclast (EMS Electro Medical...
This study randomized 252 patients, 129 to radial ESWT and 122 to sham treatment. Patients had heel pain for at least 6 months and had failed at least 2 nonpharmacologic and 2 pharmacologic treatments before study entry. 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% reduction 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 treatment outcome, 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 Component Summary score 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) show inconsistent results. Several RCT compared ESWT with an active alternative, endoscopic plantar fasciotomy. It 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-to-100 VAS of morning pain, the American Orthopaedic Foot and Ankle (AOFAS) Ankle-Hindfoot Scale score, and patient subjective assessment using the 4-item RM score. Over the 1-year follow-up, both groups improved significantly on each outcome parameter, with no significant differences between groups. The percentages of patients achieving a least a 50% reduction in the AOFAS score were 74% (25/34) in the ESWT group and 68% (21/31) in the surgery group (p=0.79). Success rates at 1 year, defined as a patient-reported good or excellent outcome based on RM score, were reached in 70.6% (24/34) of the ESWT group and in 77.4% (24/31) of the surgery group. At 2-year follow-up, the proportion 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-year follow-up, the percentage reporting success was 80% (20/25) in the surgery group and 48% (11/23) in the ESWT group (p=0.021).
Nonrandomized Studies
Nonrandomized studies have also reported outcomes after ESWT for plantar fasciitis, but given the availability of randomized trials, such studies do not provide additional evidence on ESWT’s efficacy compared with alternatives.

Section Summary: ESWT for Plantar Fasciitis
Numerous RCTs, including several well-designed double-blinded RCTs, have evaluated ESWT for treatment of plantar fasciitis. The evidence is mixed, with some studies reporting a benefit and others not. Reasons for this variability in the literature are not clear. In studies that report a benefit, the magnitude of effect for 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.

ESWT for Lateral Epicondylitis (Tendinitis of the Elbow)

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 next. Three trials used low-energy ESWT, and 1 used high-energy ESWT. Two trials reported positive effects on pain, 1 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-to-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 in the active treatment group compared with a 30% improvement in the placebo group (p<0.05).
- Rompe et al randomized 78 tennis players to 3 treatments at weekly intervals of low-energy or sham ESWT. Outcomes included pain ratings during wrist extension and Thomsen Provocation Test score, RM score, UEFS score, grip strength, and satisfaction with return to activities. At 3-month follow-up, the ESWT group, compared with 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 with 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 a 50% improvement on investigator- and patient-assessed pain on a 0-to-10 VAS and no or rare use of pain medication. At the 8-week follow-up, the ESWT group had a greater rate of
treatment success (35%) than the placebo group (22%; p < 0.05). The main driver for group differences in treatment success was the investigator-assessed pain (48% vs 29%, respectively; p < 0.01); improvements in self-assessment of pain (81% vs 70%, respectively; p = 0.06) and nonuse of pain medication (81% vs 70%, respectively; p = 0.09) were only marginal.

- Haake et al randomized 272 patients to 3 sessions of low-energy or sham ESWT. Treatment success was defined as achieving an RM score of 1 or 2 with no need for 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 the 12-week (31.7% ESWT vs 33.1% placebo) or 1-year (65.7% ESWT vs 65.3% placebo) follow-ups. Moreover, the groups did not differ on any of 5 pain assessment measures or on grip strength.

Other systematic reviews published since the 2004 Assessment have reached 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 treatment group from 7.4 to 3.8; among placebo patients, dropped from 7.6 to 5.1. A reduction in pain on the Thomsen Provocation Test of at least 50% was demonstrated in 61% of those treated compared with 29% 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—a 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 with ESWT is unclear.

In 2008, Staples et al reported a double-blind controlled trial of ultrasound-guided ESWT for epicondylitis in 68 patients. Patients were randomized to 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.\(^{26}\) 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.\(^{27}\) 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.\(^{28}\) However, this trial may have been underpowered to detect a difference.

**Nonrandomized Studies**

Nonrandomized observational studies have reported functional outcomes after ESWT for epicondylitis\(^ {29}\); however, these studies provided limited evidence on the effectiveness of ESWT for lateral epicondylitis compared with other therapies.

**Section Summary: ESWT for Lateral Epicondylitis (Tendinitis of the Elbow)**

The most direct evidence on the use of ESWT to treat lateral epicondylitis comes from multiple small RCTs, which 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.

**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.\(^ {30}\) 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.\(^ {31}\) 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. All 7 studies comparing ESWT with placebo for calcific tendinitis 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. Eight studies comparing high- with low-energy ESWT for calcific tendinitis did not demonstrate significant improvements in pain outcomes, although shoulder function was improved. Trials were reported to be generally of low quality with a high risk of bias.

In another 2014 meta-analysis of RCTs comparing high-energy ESWT with low-energy ESWT, Verstraelen et al evaluated 5 studies (total N=359 patients) on calcific shoulder tendinitis. Three 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 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: ESWT for Shoulder Tendinopathy
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. Selected for the review were 4 small RCTs and 2 cohort studies. Satisfactory evidence was found in 4 studies demonstrating the effectiveness of ESWT in the treatment of Achilles tendinopathy at 3 months. However, 2 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 et al 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 sports 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 radial ESWT and half to sham ESWT.\textsuperscript{40} The primary end point was AOFAS score measuring function, pain, and alignment and pain on a VAS. 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 suggested that the AOFAS 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 that included a review of 7 articles.\textsuperscript{42} 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 ESWT appeared to be a safe and promising treatment but that a treatment protocol could not be recommended and further basic and clinical research was 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.\textsuperscript{43}

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.\textsuperscript{41} The 2 RCTs 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 for Medial Tibial Stress Syndrome**

In 2010, Rompe et al published a report on the use of ESWT in medial tibial stress syndrome (MTSS), commonly known as “shin splints.”\textsuperscript{44} In this nonrandomized cohort study, 47 patients with MTSS for at least 6 months received 3 weekly sessions of radial ESWT and were compared with 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 with 30\% (14/47) in the control group. 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 for osteonecrosis (avascular necrosis) of the femoral head was conducted by Alves et al in 2009. Only 5 articles, all from non-U.S. sites, were identified: 2 RCTs, 1 comparative study, 1 open-label study, and 1 case report (total N=133 patients). Several studies were from 1 center in Taiwan. Of the 2 RCTs, 1 (N=48) was randomized to the use of concomitant alendronate; ESWT treatments were in both arms of the study and therefore was not the comparator. The other RCT compared ESWT with a standard surgical procedure. All results noted a reduction in pain during the study, which was attributed by author groups to a positive effect of ESWT. However, the authors of the systematic review noted the limitations of the available evidence: lack of double-blind designs, small numbers of patients included, short durations of follow-up, and nonstandard intervention (eg, energy level, number of treatments).

A comparative study not included in the Alves systematic review is that by Chen et al. In this small study, for each of 17 patients with bilateral hip osteonecrosis, 1 side was treated with total hip arthroplasty while the other was treated with ESWT. Each patient was evaluated at baseline and after treatment using 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, which also appeared to be reduced. The authors then compared the ESWT-treated data with 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 (range, 6-36 months); in all but 1 case, surgery preceded ESWT. Therefore, conclusions about the superiority of 1 intervention over the other cannot be made.

**Section Summary: ESWT for Osteonecrosis of the Femoral Head**
A limited body of evidence addresses ESWT for osteonecrosis of the femoral head, including 2 small RCTs. The available evidence is insufficient to permit conclusions about the efficacy of ESWT for osteonecrosis.

**ESWT for Nonunion or Delayed Union of Acute Fracture**
In 2010, Zelle et al reviewed the English and German medical literature for studies of ESWT for the treatment of fractures and delayed union/nonunion, restricted to studies with more than 10 patients. Ten case series and 1 RCT were identified. The 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 concluded 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 et al 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 6 months, patients who had received ESWT had VAS scores of 1.19 compared with 2.47 in the control group (p<0.001); mean percentage of weight bearing at 6 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 with 20% (6/30) in the control group (p<0.001). The authors noted some limitations to the trial: the small number of patients enrolled, surgeries performed by multiple surgeons, and questions about adequacy of randomization.

One RCT of ESWT compared with surgery for nonunion of long bone fractures was identified. Cacchio et al allocated 126 patients to 3 groups: low- or high-energy ESWT therapy, or surgery. Patients were identified for participation if referred to 1 of 3 Italian centers with nonunion fractures, here defined as at least 6 months without evidence of radiographic healing. The primary end point was radiographic evidence of healing. Secondary end point data of pain and functional status were collected by blinded evaluators. Neither patients nor treating physicians were blinded. At 6 months, healing rates in the lower energy ESWT, higher energy ESWT, and surgical arms were similar (70%, 71%, 73%, respectively). There were no significant differences among the groups at this stage. All groups’ healing rates improved at 12- and 24-month follow-ups, without significant between-group differences. Secondary end points of pain and disability were also similar. Lack of blinding may have led to differing levels of participation in other aspects of the treatment protocol.

Section Summary: ESWT for Nonunion or Delayed Union of Acute Fracture
The evidence on 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 permit conclusions on 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 postintervention Modified Ashworth Scale (MAS) scores. Five studies were selected, 4 examining spasticity in the ankle.
plantarflexor and 1 examining spasticity in the wrist and finger flexors; 3 studies evaluated poststroke 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 poststroke 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 poststroke 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 Brunstrom Recovery Stage tool to assess motor recovery, and the neurophysiological measure of $H_{\text{max}}/M_{\text{max}}$ 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 posttherapy, 1 week posttherapy, and 5 weeks posttherapy, respectively; p<0.05). $H_{\text{max}}/M_{\text{max}}$ 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 poststroke spasticity.

Santamato et al evaluated outcomes after a single session of ESWT for poststroke plantarflexor 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 (previously described) by Mani-Babu et al 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.

**Table 3. Summary of Key Trials**

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<td>Jun 2015 (completed)</td>
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</table>

NCT: national clinical trial.

Denotes industry-sponsored or cosponsored trial.

**Summary of Evidence**
For individuals who have plantar fasciitis who receive extracorporeal shock wave therapy (ESWT), the evidence includes numerous randomized controlled trials (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 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.

**Supplemental Information**

**Practice Guidelines and Position Statements**

**American College of Foot and Ankle Surgeons**
In 2010, Thomas et al published a revised practice guideline on the treatment of heel pain on behalf of the American College of Foot and Ankle Surgeons. This guideline identifies ESWT as a third tier treatment modality in patients who have failed other interventions, including steroid injection. The guideline recommends ESWT as a reasonable alternative to surgery.
National Institute for Health and Clinical Excellence
The National Institute for Health and Clinical Excellence has published guidance on ESWT for a number of applications.

- The guidance issued in November 2003 states that current evidence on safety and efficacy for treatment of calcific tendonitis of the shoulder “appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.”\(^{58}\)
- The guidances issued in August 2009 state that current evidence on the efficacy of ESWT for refractory tennis elbow, Achilles tendinopathy, and plantar fasciitis “is inconsistent and the procedure should only be used with special arrangements for clinical governance, consent and audit or research.”\(^{59-61}\)
- The guidance issued in January 2011 states that evidence on the efficacy and safety of ESWT for refractory greater trochanteric pain syndrome “is limited in quality and quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.”\(^{62}\)

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.\(^{63}\) 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 in this bulletin does not support the use of this technology for this condition.” Similarly, a 2007 report by CADTH on ESWT for chronic lateral epicondylitis noted that results from randomized trials have been conflicting and half of the studies showed no benefit over placebo for any outcome measures.\(^{64}\) 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 the 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.”\(^{65}\)

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Extracorporeal shock wave treatment for musculoskeletal indications TEC Assessments. 2003;Volume 18, Tab 5.


Billing Coding/Physician Documentation Information

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<th>Code</th>
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<td>0102T</td>
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</table>

ICD-10 Codes

- M72.2: Plantar fascial fibromatosis (plantar fasciitis)
- M75.20- M75.22: Bicipital tendinitis code range
- M75.30- M75.32: Calcific tendinitis of shoulder code range
- M77.00- M77.02: Medial epicondylitis code range
- M77.10- M77.12: Lateral epicondylitis code range
- M84.311- M84.38: Stress fracture code range
- M87.051- M87.059: Idiopathic aseptic necrosis of femur code range
- S32.2xxK-S32.9xxK: Fracture nonunion codes for the appendicular skeleton – 7th digit “K” is subsequent encounter for nonunion (in forearm, femur, lower leg & ankle fractures 7th digits “M” and “N” are also nonunion for certain types of open fractures – in fractures of the shoulder, humerus, wrist, hand and foot there isn’t separation of open vs. closed nonunions).
Policy Implementation/Update Information

5/1/01  New policy added to the Medical section. Prior authorization required; medically necessary with criteria.
3/1/02  No policy statement changes. Prior authorization is not required; predetermination is recommended.
3/1/03  No policy statement changes.
6/1/04  Policy statement revised to indicate ESWT is considered investigational. Predetermination recommendation removed.
3/1/05  No policy statement changes.
9/1/05  No policy statement changes.
3/1/06  Description section expanded, rationale updated.
9/1/06  No policy statement changes.
3/1/07  No policy statement changes.
9/1/07  No policy statement changes.
9/1/08  No policy statement changes.
9/1/09  Policy statement updated to include radial ESWT.
9/1/10  No policy statement changes.
9/1/11  No policy statement changes.
9/1/12  No policy statement changes.
9/1/13  No policy statement changes.
9/1/14  No policy statement changes.
9/1/15  Editorial changes made for clarity to policy statements; intent of policy statements unchanged.
9/1/16  No policy statement changes.

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