

# Protocol

## Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

(20140)

<b>Medical Benefit</b>		<b>Effective Date:</b> 01/01/13	<b>Next Review Date:</b> 05/23
<b>Preauthorization</b>	No	<b>Review Dates:</b> 02/07, 11/07, 11/08, 03/09, 01/10, 01/11, 01/12, 09/12, 07/13, 07/14, 07/15, 07/16, 07/17, 07/18, 07/19, 07/20, 07/21, 05/22	

### **Preauthorization is not required.**

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

### **RELATED PROTOCOLS**

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<b>Populations</b>	<b>Interventions</b>	<b>Comparators</b>	<b>Outcomes</b>
Individuals: • With plantar fasciitis	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Conservative therapy (e.g., stretching, heel supports) • Nonsteroidal anti-inflammatory therapy • Local corticosteroid injection	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With lateral epicondylitis	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Conservative therapy (e.g., physical therapy, rest) • Nonsteroidal anti-inflammatory therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With shoulder tendinopathy	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Conservative therapy (e.g., physical therapy, rest) • Nonsteroidal anti-inflammatory therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With Achilles tendinopathy	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Conservative therapy (e.g., heel lift, rest) • Nonsteroidal anti-inflammatory therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With patellar tendinopathy	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Conservative therapy (e.g., icing, support) • Nonsteroidal anti-inflammatory therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With medial tibial stress syndrome	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Conservative therapy (e.g., icing, support)	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With osteonecrosis of the femoral head	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Medication therapy (e.g., alendronate) • Hip arthroplasty	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • Acute fracture nonunion or delayed union	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Surgical therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity
Individuals: • With spasticity	Interventions of interest are: • Extracorporeal shock wave therapy	Comparators of interest are: • Medication therapy • Intrathecal medication therapy	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity

## DESCRIPTION

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

## SUMMARY OF EVIDENCE

For treatment of plantar fasciitis using ESWT, numerous randomized controlled trials (RCTs) were identified, including several well-designed double-blinded RCTs, that evaluated ESWT for the treatment of plantar fasciitis. Several systematic reviews and meta-analyses have been conducted, covering numerous studies, including studies that compared ESWT with corticosteroid injections. Pooled results were inconsistent. Some meta-analyses reported that ESWT reduced pain, while others reported nonsignificant pain reduction. Reasons for the differing results included lack of uniformity in the definitions of outcomes and heterogeneity in ESWT protocols (focused versus radial, low- versus high-intensity/energy, number and duration of shocks per treatment, number of treatments, and differing comparators). Some studies reported significant benefits in pain and functional im-

provement at 3 months, but it is not evident that the longer-term disease natural history is altered with ESWT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

For individuals who have shoulder tendinopathy who receive ESWT, a number of small RCTs, summarized in several systematic reviews and meta-analyses, comprise the evidence. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Network meta-analyses focused on 3 outcomes: pain reduction, functional assessment, and change in calcific deposits. One network meta-analysis separated trials using high-energy focused shock wave (H-FSW), low-energy focused shock wave, and radial shock wave (RSW). It reported that the most effective treatment for pain reduction was ultrasound-guided needling, followed by RSW and H-FSW. The only treatment showing a benefit in functional outcomes was H-FSW. For the largest change in calcific deposits, the most effective treatment was ultrasound-guided needling followed by RSW and H-FSW. Although some trials have reported a benefit for pain and functional outcomes, particularly for high-energy ESWT for calcific tendinopathy, many available trials have been considered poor quality. More high-quality trials are needed to determine whether ESWT improves outcomes for shoulder tendinopathy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

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

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

For individuals who have osteonecrosis of the femoral head who receive ESWT, the evidence includes 3 systematic reviews of small, mostly nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Many of the studies were low quality and lacked comparators. While most studies reported favorable outcomes with ESWT, limitations such as heterogeneity in the treatment protocols, patient populations, and lengths of follow-up make conclusions on the efficacy of ESWT for osteonecrosis uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

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

## POLICY

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

## POLICY GUIDELINES

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

## BACKGROUND

### CHRONIC MUSCULOSKELETAL CONDITIONS

Chronic musculoskeletal conditions (e.g., 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 calcific deposits by shock waves may loosen adjacent structures and promote resorption of calcium, thereby decreasing pain and improving function.

### Plantar Fasciitis

Plantar fasciitis is a 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 persists, 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 is unproven that heel spurs cause the pain. Asymptomatic heel spurs can be found in up to 10% of the population.

### Tendinitis and Tendinopathies

Common tendinitis and tendinopathy syndromes are summarized in Table 1. Many tendinitis and tendinopathy syndromes are related to overuse injury.

Table 1. Tendinitis and Tendinopathy Syndromes

Disorder	Location	Symptoms	Conservative Therapy	Other Therapies
Lateral epicondylitis (“tennis elbow”)	Lateral elbow (insertion of wrist extensors)	Tenderness over lateral epicondyle and proximal wrist extensor muscle mass; pain with resisted wrist extension with elbow in full extension; pain with passive terminal wrist flexion with elbow in full extension	<ul style="list-style-type: none"> <li>•Rest</li> <li>•Activity modification</li> <li>•NSAIDs</li> <li>•Physical therapy</li> <li>•Orthotic devices</li> </ul>	Corticosteroid injections; joint débridement (open or laparoscopic)
Shoulder tendinopathy	Rotator cuff muscle tendons, most commonly supraspinatus	Pain with overhead activity	<ul style="list-style-type: none"> <li>•Rest</li> <li>•Ice</li> <li>•NSAIDs</li> <li>•Physical therapy</li> </ul>	Corticosteroid injections
Achilles tendinopathy	Achilles tendon	Pain or stiffness 2-6 cm above the posterior calcaneus	<ul style="list-style-type: none"> <li>•Avoidance of aggravating activities</li> <li>•Ice when symptomatic</li> <li>•NSAIDs</li> <li>•Heel lift</li> </ul>	Surgical repair for tendon rupture
Patellar tendinopathy (“jumper’s knee”)	Proximal tendon at lower pole of patella	Pain over anterior knee and patellar tendon; may progress to tendon calcification and/or tear	<ul style="list-style-type: none"> <li>•Ice</li> <li>•Supportive taping</li> <li>•Patellar tendon straps</li> <li>•NSAIDs</li> </ul>	

NSAIDs: nonsteroidal anti-inflammatory drugs.

### Fracture Nonunion and Delayed Union

The definition of a fracture nonunion remains controversial, particularly the duration necessary to define nonunion. One proposed definition is a failure of progression of fracture healing for at least three consecutive months (and at least six months after the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing). The following criteria to define nonunion were used to inform this protocol:

- at least three months 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 limitation.

The 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 three 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

Other musculoskeletal conditions include medial tibial stress syndrome, osteonecrosis (avascular necrosis) of the femoral head, coccydynia, and painful stump neuromas. Neurologic conditions include spasticity, which refers to a motor disorder characterized by increased velocity-dependent stretch reflexes. It is a characteristic of upper motor neuron dysfunction, which may be due to a variety of pathologies.

### Treatment

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 one year in some cases.

For tendinitis and tendinopathy syndromes, conservative treatment often involves rest, activity modifications, physical therapy, and anti-inflammatory medications (see Table 1).

### *Extracorporeal Shock Wave Therapy*

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

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

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

## REGULATORY STATUS

Selected ESWT devices have been approved or cleared by FDA are included in Table 2.

Table 2. FDA approved Extracorporeal Shock Wave Therapy Devices

Device Name	Approval Date	Delivery System Type	Indication
OssaTron® device (HealthTronics)	2000	Electrohydraulic delivery system	<ul style="list-style-type: none"> <li>Chronic proximal plantar fasciitis, ie, pain persisting more than six months and unresponsive to conservative management</li> <li>Lateral epicondylitis</li> </ul>
Epos™ Ultra (Dornier)	2002	Electromagnetic delivery system	Plantar fasciitis
Sonocur® Basic (Siemens)	2002	Electromagnetic delivery system	Chronic lateral epicondylitis (unresponsive to conservative therapy for more than six months)
Orthospec™ Orthopedic ESWT	2005	Electrohydraulic	Chronic proximal plantar fasciitis in patients ≥18 y

Device Name	Approval Date	Delivery System Type	Indication
(Medispec)		spark-gap system	
Orbasone™ Pain Relief System (Orthometrix)	2005	High-energy sonic wave system	Chronic proximal plantar fasciitis in patients ≥18 y
Duolith® SD1 Shock Wave Therapy Device (Storz Medical AG)	2016	Electromagnetic delivery system	Chronic proximal plantar fasciitis in patients ≥18 y with history of failed alternative conservative therapies more than six months

FDA: U.S. 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 (1,300 mJ/mm<sup>2</sup>). This painful procedure requires anesthesia. A low-dose protocol consists of multiple treatments, spaced 1 week to 1 month apart, in which lower dose shock waves are applied. This protocol does not require anesthesia. The FDA labeled indication for the OssaTron® and Epos™ Ultra devices specifically describes a high-dose protocol, while the labeled indication for the Sonocur® device describes a low-dose protocol.

In 2007, Dolorclast® (EMS Electro Medical Systems), a radial ESWT, was approved by FDA through the premarket approval process. Radial ESWT is generated ballistically by accelerating a bullet to hit an applicator, which transforms the kinetic energy into radially expanding shock waves. Radial ESWT is described as an alternative to focused ESWT and is said to address larger treatment areas, thus providing potential advantages in superficial applications like tendinopathies. The FDA approved indication is for the treatment of patients 18 years and older with chronic proximal plantar fasciitis and a history of unsuccessful conservative therapy. FDA product code: NBN.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

## REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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