Protocol

Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

(20140)

Medical Benefit		**Effective Date**: 01/01/13	**Next Review Date**: 07/18
Preauthorization	No	**Review Dates**: 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	

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.

Populations	Interventions	Comparators	Outcomes
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
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

Populations	Interventions	Comparators	Outcomes
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 that may be used to treat pain using 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 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.

Summary of Evidence

For individuals who have plantar fasciitis who receive ESWT, the evidence includes two recent systematic reviews containing nine randomized controlled trials (RCTs) each (eight overlapping RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. While most of the same trials are included in both meta-analyses, pooled results were inconsistent. One meta-analysis reported that ESWT was beneficial in improving pain reduction, while the other reported nonsignificant findings in pain reduction. Reasons for the differing results include lack of uniformity in the definitions of outcomes, and heterogeneity in ESWT protocols (focused vs. radial, number and duration of shocks per treatment, the number of treatments). The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals who have shoulder tendinopathy who receive ESWT, the evidence includes two recent network meta-analyses as well as several systematic reviews and meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The network meta-analyses focused on three outcomes: pain reduction, functional assessment, and change in calcific deposits. One network meta-analysis separated trials using high-energy focused ESWT (H-FSW), low-energy ESWT, and radial ESWT (RSW). This analysis reported the most effective treatment for pain reduction was ultrasound-guided needling, followed by RSW and H-FSW. The only treatment showing a benefit in functional outcomes was H-FSW. For the largest change in calcific deposits, the most effective treatment was ultrasound-guided needling, followed by RSW, then H-FSW. Many of the RCTs are considered poor quality. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have Achilles tendinopathy who receive ESWT, the evidence includes systematic reviews of RCTs and nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. In the most recent systematic review, a pooled analysis reported that ESWT reduced both short- and long-term pain compared with nonoperative treatments, although the authors warned that results were inconsistent across the RCTs and that there was heterogeneity across studies in 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals who have medial tibial stress syndrome who receive ESWT, the evidence includes a small RCT and a small nonrandomized cohort study. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The RCT reported no difference in self-reported pain between study groups. The cohort study reported improvements with ESWT, although selection bias impacts the strength of the conclusions. The available evidence is limited and inconsistent; it does not permit conclusions about the benefits of ESWT for medial tibial stress syndrome. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

For individuals who have nonunion or delayed union who receive ESWT, the evidence includes a systematic review of a RCT and several case series, as well as two RCTs published after the systematic review. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The review concluded that the evidence was inconsistent and of poor quality. Data pooling was not possible due

to the heterogeneity of outcome definitions and treatment protocols. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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, delayed union and non-union of fractures, avascular necrosis of the femoral head; 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

Extracorporeal Shock Wave Therapy

Also known as orthotripsy, 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. 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 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 in the mechanism of 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. Food and Drug Administration (FDA) approval was first granted in 2002 for focused ESWT devices and in 2007 for RSW devices.

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 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. 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.

Tendinitis and Tendinopathies

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

Table 1: Tendinitis and Tendinopathy Syndromes

Disorder	Location	Symptoms	Conservative Therapy	Other Therapies
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 elbow in full extension; pain with passive terminal wrist flexion with 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 • Ice when symptomatic • NSAIDs • Heel lift	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	• Ice • 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 the duration necessary to define a

condition of nonunion. One proposed definition is 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). For our purposes, the following criteria were used to define nonunion:

- at least three months have passed since the date of fracture;
- serial radiographs have confirmed that no progressive signs of healing have occurred;
- the fracture gap is one cm or less; and
- the patient can be adequately immobilized and is of an age likely to comply with nonweight 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 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

ESWT has been investigated for various 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, six 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

Device Name	Approval Date	Delivery System Type	Indication
OssaTron® device (HealthTronics, Marietta, GA)	2000	Electrohydraulic delivery system	• Chronic proximal plantar fasciitis, i.e., pain persisting greater than six months and unresponsive to conservative management • Lateral epicondylitis
Epos™ Ultra (Dornier, Germering, Germany)	2002	Electromagnetic delivery system	Plantar fasciitis
Sonocur® Basic (Siemens, Erlangen, Germany)	2002	Electromagnetic delivery system	Chronic lateral epicondylitis (unresponsive to conservative therapy for greater than six months)
Orthospec™ Orthopedic ESWT (Medispec, Germantown, MD)	2005	Electrohydraulic spark-gap system	Chronic proximal plantar fasciitis in patients 18 years or older
Orbasone™ Pain Relief System (Orthometrix, White Plains, NY)	2005	High-energy sonic wave system	Chronic proximal plantar fasciitis in patients 18 years or older
Duolith® SD1 Shock Wave Therapy Device (Storz Medical AG, Switzerland)	2016	Electromagnetic delivery system	Chronic proximal plantar fasciitis in patients 18 years or older with history of failed alternative conservative therapies greater than six months

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/mm^2). 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.

In May 2007, Dolorclast® (EMS Electro Medical Systems; Nyon, Switzerland), another type of ESWT called 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.

Related Protocols

Electrical Bone Growth Stimulation of the Appendicular Skeleton

Ultrasound Accelerated Fracture Healing Device

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

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

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