The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Use Management.* 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.

### Description

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.

### 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 mechanisms are also thought to be involved. Physical stimuli are known to activate endogenous pain control systems, and activation by shock waves may “reset” the endogenous pain receptors. Damage to 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.

Conservative therapy of plantar fasciitis is successful in the vast majority of cases. Rest or minimization of running or jumping is the cornerstone of therapy. Heel cups are sometimes helpful in alleviating symptoms,
presumably by padding the heel and absorbing the impact of walking. Nonsteroidal anti-inflammatory drugs are also helpful in acute cases. If these measures are ineffective, a local injection of steroids may be effective. Improvement is frustratingly slow and gradual, taking up to one year in some cases.

**Tendinitis of the Elbow (Lateral Epicondylitis)**

Lateral epicondylitis is the most common form of tendinitis of the elbow and results in lateral elbow pain and functional limitations. The disorder is caused by overuse or injury of the tendons that attach the arm muscles to the elbow, such as commonly occurs from playing tennis (“tennis elbow”). However, only a minority of cases is caused by playing tennis; the majority occurs from other activities that involve repetitive extension of the wrist. Overuse of the extensor muscles leads to microtears at their insertion point, which incites an inflammatory response. Repetitive cycles of injury and inflammation lead to tendinosis, degeneration of the tendon structures, and disorganized healing.

The diagnosis of lateral epicondylitis is made by characteristic pain and tenderness at the lateral aspect of the elbow, in conjunction with typical activities or injury that accompany this condition. Radiologic imaging is not necessary for diagnosis but may be useful in ruling out other causes of lateral elbow pain, such as fracture, dislocation, degenerative joint disease, and other bony or soft tissue pathologies. Imaging is usually normal in lateral epicondylitis, although occasionally calcium deposition can be seen.

Conservative treatment consists of rest, activity modification, anti-inflammatory medications, and/or physical therapy. Corticosteroid injections and orthotic devices can also be tried as adjuncts to conservative measures. A number of surgical treatments are available for patients who do not respond to conservative treatment; approximately 5–10% of patients with tendinitis of the elbow require surgery. Surgery may be performed as open or laparoscopic procedures. The general approach is to debride any degenerative or nonviable tissue and to repair tears or other structural abnormalities.

**Nonunion and Delayed Union**

The definition of a fracture nonunion has remained controversial, particularly in the necessary duration to define a condition of nonunion. Complicating variables that may impact healing time include the degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock. The time period has been variously described as lack of visible signs of healing within three months, six months, or nine months. The lack of agreement on the clinical definition of nonunion arises from study populations that have been heterogeneous, and therefore comparisons between studies are difficult. The nonunion fracture can be further defined as atrophic, in which no callus formation occurs, or hypertrophic, with callus formation at both sides of the fracture, but without fusion. Delayed union refers to a decelerating bone healing process, as identified in serial x-rays. (In contrast, nonunion serial x-rays show no evidence of healing.) When grouped together, delayed union and nonunion are sometimes referred to as ununited fractures.

**Regulatory Status**

Currently, five ESWT devices are approved for marketing by the U.S. Food and Drug Administration (FDA). The OssaTron® device (HealthTronics, Marietta, GA), an electrohydraulic delivery system was approved by the FDA on July 20, 2000, for patients with chronic proximal plantar fasciitis—i.e., pain persisting more than six months and not responding to conservative management. It is also FDA-approved for treatment of lateral epicondylitis (tennis elbow). The Epos™ Ultra (Dornier, Germering, Germany), an electromagnetic delivery system, was approved by the FDA on January 15, 2002, for plantar fasciitis. The SONOCUR® Basic (Siemens, Erlangen, Germany) also uses an electromagnetic delivery system and was approved by the FDA for use in chronic lateral epicondylitis (symptoms unresponsive to conservative therapy for more than six months) on July 19, 2002. In 2005, the Orthospec™ Orthopedic ESWT (Medispec Ltd., Germantown, MD), an electrohydraulic spark-gap
device, and the Orbasone™ Pain Relief System (Orthometrix, White Plains, NY), a high-energy sonic wave system, received approval for treatment of chronic proximal plantar fasciitis in patients 18 years of age or older.

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/mm²). This painful procedure requires anesthesia. A low-dose protocol consists of multiple treatments, spaced one week to one month apart, in which a lower dose of shock waves is applied. This protocol does not require anesthesia. The FDA-labeled indication for the OssaTron® and Epos™ Ultra device specifically describes a high-dose protocol, while the labeled indication for the SONOCUR® device describes a low-dose protocol.

Another type of ESWT, radial ESWT (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.

Related Protocols:
- Ultrasound Accelerated Fracture Healing Device
- Electrical Bone Growth Stimulation of the Appendicular Skeleton
- Bone Morphogenetic Protein

Corporate Medical Guideline

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 (epicondylitis, tennis elbow), stress fractures, delayed union and non-union of fractures, and avascular necrosis of the femoral head.

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.

References

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


