**Medical Coverage Policy |** Extracorporeal Shock Wave Therapy for Plantar Fasciitis and Other Musculoskeletal Conditions

**EFFECTIVE DATE:** 10|01|2015
**POLICY LAST UPDATED:** 12|06|2016

## OVERVIEW

Extracorporeal shock wave therapy (ESWT) is a noninvasive method that may be used to treat pain using shock waves or sound waves that are 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.

## MEDICAL CRITERIA

Not applicable

## PRIOR AUTHORIZATION

Not applicable

## POLICY STATEMENT

**BlueCHiP for Medicare and Commercial Products**

Extracorporeal shock wave therapy, using either a high- or low-dose protocol or radial ESWT, is considered not medically necessary 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; spasticity; stress fractures; delayed union and nonunion of fractures; and avascular necrosis of the femoral head, due to a lack of peer-reviewed scientific literature that demonstrates the service is effective.

## COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary**.**

## BACKGROUND

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. 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, 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 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 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 nonunion of bone fractures.

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

**Tendinitis and Tendinopathies**
ESWT has been investigated for a variety of tendinitis/tendinopathy syndromes, such as lateral epicondylitis (elbow tendinitis/"tennis elbow"), shoulder tendinopathy, achilles tendinopathy, and patellar tendinopathy ("jumper's knee"). Many tendinitis/tendinopathy syndromes are related to overuse injury. Conservative treatment often involves rest, activity modifications, physical therapy, and anti-inflammatory medications.

**Fracture Nonunion and Delayed Union**
The following criteria are used to define fracture 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 healing.) 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.

Currently, the following 6 ESWT devices for orthopedic use are approved for marketing by the U.S. Food and Drug Administration (FDA):

- OssaTron® device (HealthTronics, Marietta, GA) - Approval date: 2000. Delivery system: Electrohydraulic. Indications: chronic proximal plantar fasciitis, i.e., pain persisting >6 months and not responding to conservative management; lateral epicondylitis
- Epos™ Ultra (Dornier, Germering, Germany) - Approval date: 2002. Delivery system: Electromagnetic. Indications: plantar fasciitis.
- SONOCUR® Basic (Siemens, Erlangen, Germany) - Approval date: 2002. Delivery system: Electromagnetic. Indications: chronic lateral epicondylitis (unresponsive to conservative therapy for >6 months)

- Orthospec™ Orthopedic ESWT (Medispec Ltd., Germantown, MD) - Approval date: 2005. Delivery system: Electrohydraulic spark-gap. Indications: Chronic proximal plantar fasciitis in patients ≥18 years of age.
- Orbasone™ Pain Relief System (Orthometrix, White Plains, NY) - Approval date: 2005. Delivery system: High-energy sonic wave. Indications: Chronic proximal plantar fasciitis in patients ≥18 years of age.
- Duolith® SD1 Shock Wave Therapy Device (Storz Medical AG, Switzerland) - Approval date: 2016. Delivery system: Electromagnetic. Indications: Chronic proximal plantar fasciitis in patients ≥18 years of age with history of failed alternative
conservative therapies >6 mo

Both high-dose and low-dose protocols have been investigated. A high-dose protocol consists of a single treatment of high-energy shock waves (1300mJ/mm-2). This painful procedure requires anesthesia and is performed in a hospital or ambulatory surgery center. 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 and is usually used in the office. 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. 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.

ESWT has been investigated for use in a variety of musculoskeletal conditions. Given the limitations in the evidence base, ESWT is considered not medically necessary for the treatment of musculoskeletal conditions including plantar fasciitis, tendinopathies, (lateral epicondylitis, patellar tendinopathy, Achilles tendinopathy, and shoulder tendinopathy), spasticity, medial tibial stress syndrome, osteonecrosis of the femoral head, and for prevention or treatment of fracture nonunion or delayed union.

## CODING

**BlueCHiP for Medicare and Commercial Products**

The following CPT codes are considered not medically necessary:

**28890**
**0019T** (Code deleted effective 12/31/2016)
**0101T**
**0102T**

To report extracorporeal shock wave therapy, low energy involving musculoskeletal system, please use the appropriate Unlisted CPT code.

## RELATED POLICIES

Not applicable

## PUBLISHED

Provider Update, January 2017
Provider Update, August 2015
Provider Update, December 2012
Provider Update, January 2012
Provider Update, November 2010

Provider Update, September 2009
Provider Update, September 2008

## REFERENCES


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