

## Medical Policy



An Independent Licensee of the  
Blue Cross and Blue Shield Association.

### Title: Extracorporeal Shock Wave Therapy (ESWT) for Plantar Fasciitis

#### Professional

Original Effective Date: July 11, 2001  
Revision Date(s): November 5, 2001; June 14, 2002; June 13, 2003; January 28, 2004; June 10, 2004; April 21, 2005; December 15, 2005  
Current Effective Date: January 1, 2006

#### Institutional

Original Effective Date: July 1, 2005  
Revision Date(s): December 15, 2005  
Current Effective Date: January 1, 2006

#### DESCRIPTION

Extracorporeal shockwave treatment (ESWT), also known as orthotripsy, has been available since the early 1980s for the treatment of renal 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. Microtrauma induced by ESWT may promote angiogenesis and thus aid in healing.

Currently, the U.S. Food and Drug Administration (FDA) approve 3 ESWT devices.

1. 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 that has failed to respond to conservative management.
2. The Epos™ Ultra (Dornier, Germering, Germany), an electromagnetic delivery system, was approved by the FDA on January 15, 2002, for plantar fasciitis.
3. The SONOCUR® Basic (Seimans, Erlangen, Germany) also uses an electromagnetic delivery system. 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<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 a lower dose of shock waves is applied (1406mJ/mm-2 over 3 sessions). 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.

### **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 a year in some cases.

### **POLICY**

1. Minimal six months of diagnosed plantar fasciitis pain.
2. Minimal six months of active professional treatment for the plantar fasciitis including a required treatment with:
  - a. Non-steroidal anti-inflammatory drugs (NSAIDs) or
  - b. Cortisone injections and
  - c. A minimum of three (3) of the five (5) following conservative treatments:
    - Over the counter arch supports, insoles, or heel cups
    - Physical therapy, stretching, ultrasound, massage
    - Strapping immobilization
    - Night Splints
    - Custom orthotic devices
3. Failure of treatment to reasonably resolve plantar fasciitis symptoms patient continues to have intractable activity limiting pain.
4. Extracorporeal shock wave therapy (orthotripsy) is medically necessary for plantar fasciitis (heel spurs and chronic heel pain).
5. A maximum of three (3) orthotripsy treatments per each heel with at least six months between ESWT procedures on the same heel.
6. Fasciotomy should be the last procedure attempted or used in those patients who do not meet criteria for ESWT.

7. Extracorporeal shock wave therapy ESWT for chronic plantar fasciitis is comparable in relative value to a plantar fasciotomy (28008).

**DOCUMENTATION**

Medical record submission (minimal range: last six months of medical records).

**UTILIZATION**

1. The use of a high-energy (electrohydraulic or electromagnetic shock) machine approved by the FDA for chronic plantar fasciitis is covered. All other machines are considered experimental/investigational.
2. Review prior to initial and additional treatments.
3. Criteria apply to EACH heel independently.
4. Ambulatory surgery center and outpatient hospital setting are the appropriate place for service.
5. Regional and/or IV sedation is needed for pain control during the procedure

**CODING**

**REVENUE CODE**

079X

**CPT**

28890	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia
-------	--

**DIAGNOSIS**

**These diagnoses are otherwise subject to medical policy as stated above**

726.73	Calcaneal spur
728.71	Plantar fascial fibromatosis

**REVISIONS**

April 21, 2005	Added "with at least six months between ESWT procedures" to Policy #5.
December 15, 2005	In "Coding" CPT/HCPCS section, deleted CPT code 0020T and added CPT code 28890.

**REFERENCES**

1. Buchbinder R, Ptasznik R, Gordon J et al. Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis: a randomized controlled trial. JAMA 2002; 288(11):1364-72.

2. Haake M, Konig IR, Decker T et al. Extracorporeal shock wave therapy for lateral epicondylitis: a randomized multicenter trial. *J Bone Joint Surg Am* 2002; 84-A(11):1982-91.
3. Kudo P, Kainty K, Coughlin L et al. A randomized, placebo controlled, double blind clinical trial evaluating the treatment of plantar fasciitis with an extracorporeal shockwave therapy (ESWT) device: A North American confirmatory study. *Am J Sports Med* (submitted).
4. Rompe JD, Decking J, Schoellner C et al. Repetitive low-energy shock wave treatment for chronic lateral epicondylitis in tennis players. *Am J Sports Med* 2004; 32(3):734-43.
5. Rompe JD, Decking J, Schoellner C et al. Shock wave application for chronic plantar fasciitis in running athletes. A prospective, randomized, placebo-controlled trial. *Am J Sports Med* 2003; 31(2):268-75.
6. Ogden JA, Alvarez R, Levitt R et al. Shock wave therapy for chronic proximal plantar fasciitis. *Clin Orthop* 2001; 387:47-59.
7. Theodore GH, Buch M, Amendola A et al. Extracorporeal shock wave therapy for the treatment of plantar fasciitis. *Foot Ankle Int* 2004; 25(5): 290-7.

#### **Government Agency; Medical Society; and Other Authoritative Publications**

1. 2001 TEC Assessment: Extracorporeal shock wave treatment for musculoskeletal indications
2. 2003 TEC Assessment: Extracorporeal shock wave treatment for musculoskeletal indications.
3. 2004 TEC Assessment: Extracorporeal shock wave treatment for chronic plantar fasciitis.
4. Dornier Medical Systems Inc. Dornier Epos™ Ultra summary of safety and effectiveness, PMA #P000048.
5. HealthTronics Surgical Services Inc. Supplementary data including "Final report G960232 for HealthTronics OssaTron™ indicated for ESWL treatment of Chronic Proximal Plantar Fasciitis," submitted to FDA on April 6, 2001.

#### **Web Site**

1. U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health. SONOCUR® summary of safety and effectiveness available at <http://www.fda.gov/cdrh/pdf/P010039b.pdf>. Last accessed January 10, 2003.
2. U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health. OssaTron® summary of safety and effectiveness available at <http://www.fda.gov/cdrh/pdf/p990086b.pdf>. Last accessed January 14, 2003.