

*For extracorporeal shock wave treatment (ESWT) related to CPT code 0101T and 0102T, refer to LCD L38775 and Article A58367.*

*Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16- General Exclusions from Coverage for other services included in this policy.*



BlueCross BlueShield  
of Alabama

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**Name of Blue Advantage Policy:**

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

Policy #: 076

Latest Review Date: July 2023

Category: Medical

**ARCHIVED EFFECTIVE 11/1/2023**

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**BACKGROUND:**

*Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

- 1. Safe and effective;*
- 2. Not experimental or investigational\*;*
- 3. Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
  - Furnished in a setting appropriate to the patient's medical needs and condition;*
  - Ordered and furnished by qualified personnel;*
  - One that meets, but does not exceed, the patient's medical need; and*
  - At least as beneficial as an existing and available medically appropriate alternative.*

*\*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and*

necessary by Medicare. Providers should bill **Original Medicare** for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).

## **POLICY:**

### **Effective for dates of service on or after February 14, 2021:**

**For extracorporeal shock wave treatment (ESWT) related to CPT code 0101T and 0102T, refer to LCD L38775 and Article A58367.**

### **For ESWT related to CPT code 28890, refer to guidance below:**

**Blue Advantage** will treat ESWT, using either a high- or low-dose protocol or radial ESWT as a **non-covered** benefit and as **investigational** when used to treat conditions involving the plantar fascia, including but not limited to plantar fasciitis and heel spur syndrome.

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### **Effective for dates of service March 24, 2020, through February 13, 2021:**

**Blue Advantage** will treat ESWT, using either a high- or low-dose protocol or radial ESWT as a **non-covered** benefit and as **investigational** when used to treat 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 non-union of fractures, and avascular necrosis of the femoral head.

**Blue Advantage** will treat ESWT as a **non-covered** benefit and as **investigational** when used to treat chronic pelvic pain syndrome (CPPS) resulting from abacterial chronic prostatitis.

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### **Effective for dates of service February 26, 2018, through March 23, 2020, refer to LCDs L34555 & L36954**

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### **Effective for dates of service prior to February 26, 2018:**

**Blue Advantage** will treat ESWT when used to treat plantar fasciitis or other musculoskeletal conditions as a **non-covered** benefit and as **investigational when using either a high- or low-dose protocol or radial ESWT.**

*Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## **DESCRIPTION OF PROCEDURE OR SERVICE:**

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 one treatment. ESWT has been investigated for use in a variety of musculoskeletal conditions.

### 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 the table below. Many tendinitis and tendinopathy syndromes are related to overuse injury.

### 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)

Disorder	Location	Symptoms	Conservative Therapy	Other Therapies
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 3 consecutive months (and at least 6 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 review:

- at least 3 months since the date of fracture;
- serial radiographs have confirmed that no progressive signs of healing have occurred;
- the fracture gap is 1cm 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 3 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.

### **Chronic Pelvic Pain**

Prostatitis is one of the most frequent urological diagnoses, resulting in more than two million physician visits in the United States annually. Most men have the abacterial form of chronic prostatitis, or chronic pelvic pain syndrome (CPPS). Symptoms of CPPS are urinary and erectile dysfunction, pain focused in the prostate region, as well as perineal, inguinal, scrotal and suprapubic pain.

CPPS is thought to be manifested as a myofascial pain syndrome with an abnormal tone of the periprostatic musculature with neurological components.

Analgesics, anti-inflammatory agents, antibiotics,  $\alpha$ -receptor blockers and 5 $\alpha$ -reductase inhibitors are used alone and in various combinations without sufficient clarification of the evidence and effectiveness of each of these treatments. Therefore, clinicians have increasingly begun to look for non-drug treatment options. Physiotherapy, “trigger-point” massage and electromagnetic treatment have been tried.

### **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 1 year in some cases.

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

### **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 Food and Drug Administration (FDA) approval was first granted in 2002 for focused ESWT devices and in 2007 for RSW devices.

## **KEY POINTS:**

The most recent literature update covered the period through April 21, 2023. Following is a summary of key studies to date.

### **Summary of Evidence**

For treatment of plantar fasciitis using extracorporeal shock wave therapy (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-analysis 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 improvement at three 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 the effects of the technology on health outcomes.

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 UGN, 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 UGN, 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 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 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 most recent RCT found that activity-related pain was lower with ESWT at 6 weeks compared to ultrasound therapy, but there was no difference in pain at rest. 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 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 impacted 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 three 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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

### **Practice Guidelines and Position Statements**

#### **American College of Foot and Ankle Surgeons**

Thomas et al (2010) revised guidelines on the treatment of heel pain on behalf of the American College of Foot and Ankle Surgeons.<sup>80</sup> The guidelines identified extracorporeal shock wave therapy (ESWT) as a third tier treatment modality in patients who have failed other interventions, including steroid injection. The guidelines recommended ESWT as a reasonable alternative to surgery. In an update to the American College of Food and Ankle Surgeons clinical consensus statement, Schneider et al (2018) state that ESWT is a safe and effective treatment for plantar fasciitis.

#### **National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence has published guidance on ESWT for a number of applications.

- “The 2 guidance documents issued in 2009 stated that current evidence on the efficacy of ESWT for refractory tennis elbow and plantar fasciitis “is inconsistent.”
- A guidance issued in 2011 stated that evidence on the efficacy and safety of ESWT for refractory greater trochanteric pain syndrome “is limited in quality and quantity.”
- A guidance issued in 2016 stated that current evidence on the efficacy of ESWT for Achilles tendinopathy “is inconsistent and limited in quality and quantity.
- A guidance issued in 2022 stated that evidence on the efficacy of ESWT for calcific tendinopathy of the shoulder is inadequate. Despite a lack of safety concerns, the ESWT should only be used in the context of research.”

#### **U.S. Preventive Services Task Force Recommendations**

Not applicable.



**KEY WORDS:**

Extracorporeal Shock Wave, Extracorporeal Shock Wave Therapy, Extracorporeal Shock Wave Treatment, ESW, ESWT, OssaTron, Orthospec™ Orbasone™, SONOCOR, Epos™ Ultra, Extracorporeal pulse activation therapy, EPAT, D-Actor 100

**APPROVED BY GOVERNING BODIES:**

Selected ESWT devices have been approved by FDA are included in the table below.

**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 &gt;6 mo 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 >6 mo)
Orthospec™ Orthopedic ESWT (Medispec)	2005	Electrohydraulic spark-gap system	Chronic proximal plantar fasciitis in patients ≥18 y
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 >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 (1300 mJ/mm<sup>2</sup>). 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 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.

### **BENEFIT APPLICATION:**

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

### **CURRENT CODING:**

#### **CPT Codes:**

28890	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy
0102T	Extracorporeal shock wave, high energy, performed by a physician requiring anesthesia other than local, involving lateral humeral epicondyle
20999	Unlisted procedure, musculoskeletal system, general

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## **POLICY HISTORY:**

Adopted for Blue Advantage, March 2005  
 Available for comment May 1-June 14, 2005  
 Medical Policy Group, December 2006  
 Medical Policy Group, July 2007  
 Medical Policy Group, January 2009  
 Available for comment January 9-February 23, 2009  
 Medical Policy Group, March 2010  
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Medical Policy Group, July 2016  
Medical Policy Group, December 2016  
Medical Policy Group, July 2017  
Medical Policy Group, February 2018  
Medical Policy Group, April 2020: Reinstated effective March 24, 2020.  
Medical Policy Group, August 2021  
Medical Policy Group, August 2022  
Medical Policy Group, July 2023  
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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case by case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*