

Blue Cross Blue Shield of Massachusetts is an Independent Licenses of the Blue Cross and Blue Shield Association

## **Medical Policy**

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

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## **Policy Number: 081**

BCBSA Reference Number: 2.01.40 (For Plans internal use only)

#### **Related Policies**

- Bone Morphogenetic Protein, #097
- Electrical Bone Growth Stimulation of the Appendicular Skeleton, #499

#### Policy

## Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Extracorporeal shock wave therapy (ESWT), using either a high or low-dose protocol or radial ESWT, is **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;
- Avascular necrosis of the femoral head:
- Delayed union and nonunion of fractures; and
- Spasticity.

#### **Prior Authorization Information**

#### Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

#### Outpatient

For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	This is <b>not</b> a covered service.
Commercial PPO and Indemnity	This is <b>not</b> a covered service.
Medicare HMO Blue <sup>SM</sup>	This is <b>not</b> a covered service.
Medicare PPO Blue <sup>SM</sup>	This is <b>not</b> a covered service.

#### **CPT Codes / HCPCS Codes / ICD Codes**

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT codes are considered investigational for <u>Commercial Members: Managed Care</u> (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

#### **CPT Codes**

CPT codes:	Code Description
CF1 Codes.	Code Description
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 therapy; high energy, performed by a physician, requiring
	anesthesia other than local, involving lateral humeral epicondyle

#### **Description**

#### **Chronic Musculoskeletal Conditions**

Chronic musculoskeletal conditions (eg, 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 Table 1. Many tendinitis and tendinopathy syndromes are related to overuse injury.

#### Table 1. 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	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 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 1 cm or less; and
- the patient can be adequately immobilized and is of an age likely to comply with nonweightbearing 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.

#### **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 (Table 1).

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

## Summary

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 (eg, 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 1 treatment. ESWT has been investigated for use in a variety of musculoskeletal conditions.

For treatment of plantar fasciitis using extracorporeal shock wave therapy (ESWT), numerous randomized controlled trials (RCTs) were identified, including several well-designed, double-blind 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-analyses 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 vs. radial, low- vs. 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 3 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 that the technology results in an improvement in the net health outcome.

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 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 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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

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 showed no difference in self-reported pain measurements between study groups. The nonrandomized trial reported improvements with ESWT, but selection bias limited the strength of the conclusions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have osteonecrosis of the femoral head who receive ESWT, the evidence includes 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 that the technology results in an improvement in the net health outcome.

For individuals who have nonunion or delayed union who receive ESWT, the evidence includes systematic reviews, relatively small RCTs with methodologic limitations (eg, heterogeneous outcomes and treatment protocols), and 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 that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

## **Policy History**

Date	Action
8/2023	Annual review. Description, summary, and references updated. Policy statements unchanged.
8/2022	Annual review. Description, summary, and references updated. Policy statements unchanged.
12/2020	Annual review. Description, summary, and references updated. Policy statements unchanged.
8/2019	Annual review. Description, summary, and references updated. Policy statements unchanged.
7/2018	Annual review. Description, summary, and references updated. Policy statements unchanged.
7/2017	Annual review. New references added
1/2017	Clarified coding information for the 2017 code changes.
7/2016	Annual review. New references added
5/2015	Clarified coding language.
4/2015	Annual review. Editorial changes made for clarity to policy statements; intent of policy statements unchanged. Effective 4/1/2015.
5/2014	Annual review. New references added
4/2013	Annual review. New references added
11/2011- 4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
6/2011	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation and Rheumatology. No changes to policy statements.
7/2010	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation and Rheumatology. No changes to policy statements.
7/2009	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation and Rheumatology. No changes to policy statements.
3/2009	Annual Review. Radial ESWT added to non- coverage statement.
11/2008	Medical Policy 081 effective 11/2008 describing ongoing non-coverage.

### Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use Managed Care Guidelines

Indemnity/PPO Guidelines

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