MEDICAL POLICY

POLICY TITLE	EXTRACORPOREAL SHOCK WAVE TREATMENT FOR PLANTAR FASCIITIS AND OTHER MUSCULOSKELETAL CONDITIONS
POLICY NUMBER	MP-2.034

Original Issue Date (Created):	**7/1/2002**
Most Recent Review Date (Revised):	**7/2/2018**
Effective Date:	**8/1/2018**

I. POLICY

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 (lateral epicondylitis), Achilles tendinitis and patellar tendinitis; stress fractures; avascular necrosis of the femoral head; delayed union and non-union of fractures; and spasticity. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

II. PRODUCT VARIATIONS

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This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO: Refer to FEP Medical Policy Manual MP-2.01.40, Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions. The FEP Medical Policy Manual can be found at: www.fepblue.org.

III. DESCRIPTION/BACKGROUND

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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.

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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 nonweight bearing.

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

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REGULATORY STATUS

Currently, 6 focused ESWT devices have been approved by FDA through the premarket approval process for orthopedic use (see Table 2). FDA product code: NBN.

Table 2. FDA-Approved Extracorporeal Shock Wave Therapy Devices

Device Name	Approval Date	Delivery System Type	Indication
OssaTron® device (HealthTronics)	2000	Electrohydraulic delivery system	• Chronic proximal plantar fasciitis, ie, pain persisting >6 mo and unresponsive to conservative management • Lateral epicondylitis
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

FDA: Food and Drug Administration.

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^2). This painful procedure requires anesthesia. A low-dose protocol consists of multiple treatments, spaced 1 week to 1 month apart, in which lower dose shock waves are applied. This protocol does not require anesthesia. The FDA-labeled indication for the OssaTron® and Epos™ Ultra devices 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. FDA product code: NBN.

IV. RATIONALE

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Summary of Evidence

For individuals who have plantar fasciitis who receive ESWT, the evidence includes 2 recent systematic reviews containing 9 RCTs each (8 overlapping RCTs). Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. While most of the same trials were included in both meta-analyses, pooled results were inconsistent. One meta-analysis reported that ESWT was beneficial in reducing pain, while the other reported nonsignificant findings in pain reduction. Reasons for the differing results include

lack of uniformity in the definitions of outcomes, and heterogeneity in ESWT protocols (focused vs radial, number and duration of shocks per treatment, number of treatments). The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have lateral epicondylitis who receive ESWT, the evidence includes small RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Overall, although some RCTs have demonstrated benefits in pain and functional outcomes associated with ESWT, the limited amount of high-quality RCT evidence precludes conclusions about the efficacy of ESWT for lateral epicondylitis. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have shoulder tendinopathy who receive ESWT, the evidence includes 2 network meta-analyses as well as several systematic reviews and meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The 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 ESWT (H-FSW), low-energy ESWT, and radial ESWT (RSW). This analysis reported 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, then H-FSW. Many of the RCTs were judged of poor quality. 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, an RCT published after the systematic review, and nonrandomized studies. 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 studies (e.g., patient populations, 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have patellar tendinopathy who receive ESWT, the evidence includes systematic reviews of small studies, an RCT published after the systematic review, and a nonrandomized study. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The studies reported inconsistent results. Many had methodologic deficiencies such as small numbers, short follow-up periods, and heterogeneous treatment protocols. Results from a nonrandomized study suggested that the location of the patellar tendinopathy might impact the response to ESWT (patients with retropatella fat extension did not respond to RSW compared with patients with tendon

involvement). 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 2 systematic reviews of small, mostly nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. While many of the studies have suggested that ESWT might be effective in improving motor function and reducing pain, particularly in patients with early-stage osteonecrosis, the studies were judged of low quality based on lack of blinding, lack of comparators, small sample sizes, short follow-up, and variations in treatment protocols. 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 a systematic review of an RCT and several case series, as well as 2 RCTs published after the systematic review. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Reviewers concluded that the evidence was inconsistent and of poor quality. Data pooling was not possible due to the heterogeneity of outcome definitions and treatment protocols. 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. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. As a treatment for spasticity, several small studies have demonstrated ESWT provides short-term improvements in Modified Ashworth Scale scores, but direct evidence on the effect of ESWT on more clinically meaningful measures (e.g., pain, function) are lacking. Differences in treatment parameters among studies, including energy dosage, method of generating and directing shock waves, and use or absence of anesthesia, limit generalizations about the evidence base. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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FASCIOTOMY refers to a surgical incision into an area of fascia (connective tissue).

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VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered:

CPT Codes®								
0101T	0102T	20999	28890					

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90. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.01.40, Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions. June 2018.*

X. POLICY HISTORY

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MP 2.034	**CAC 3/25/03**
	CAC 5/31/05
	CAC 4/25/06
	CAC 3/27/07
	CAC 5/27/08
	CAC 5/26/09
	CAC 5-25-10 Adopted BCBSA Medical Policy. No change in policy statement.
	CAC 4/26/11 Consensus
	CAC 6/26/12 Consensus review; no changes, references updated. **7/9/12-** FEP variation revised to refer to the FEP policy manual.
	02/13/2013- Removed unlisted cod e from policy
	7.16.13 Admin Review Complete
	CAC 9/24/13 Consensus review. References updated but no changes to the policy statements**.** Rationale added.
	CAC 7/22/14 Consensus. No change to policy statements. References updated.
	CAC 7/21/15 Consensus review**.** Editorial changes made for clarity to the policy statements; intent of policy statements unchanged. Background, reference and rationale update. Codes reviewed.
	CAC 7/26/16 Consensus review. No change to policy statements. Background, references and rationale updated. Coding reviewed.
	Administrative Update 11/23/16 Variation reformatting
	Administrative Update 1/1/17: Removed end dated code 0019T and added 20999 to replace; effective 1/1/17.
	CAC 9/26/17 Consensus review. No change to the policy statement. Background,

POLICY TITLE	EXTRACORPOREAL SHOCK WAVE TREATMENT FOR PLANTAR FASCIITIS AND OTHER MUSCULOSKELETAL CONDITIONS
POLICY NUMBER	MP-2.034

	references and rationale updated**.** Medicare variation added to L35094 Services That are Not Reasonable and Necessary as Medicare considers this procedure not reasonable or necessary**.** Coding reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	7/02/18 Consensus review. Policy statement language reordered, but position unchanged. Description/Background, Rationale and Reference sections updated.

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