Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

Policy # 00039
Original Effective Date: 08/27/2001
Current Effective Date: 03/21/2018

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Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers extracorporeal shockwave therapy (ESWT), using either a high-dose or low-dose protocol or radial extracorporeal shockwave therapy (rESWT), as a treatment of musculoskeletal conditions to be **investigational*,** including but not limited to:

- Plantar fasciitis;
- Tendinopathies including tendinitis of the shoulder;
- Tendinitis of the elbow (lateral epicondylitis, tennis elbow);
- Achilles tendinitis;
- Patellar tendinitis;
- Spasticity;
- Stress fractures;
- Delayed union and non-union of fractures;
- Avascular necrosis of the femoral head.

Background/Overview

EXTRACORPOREAL SHOCK WAVE THERAPY

Also known as orthotripsy, 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. 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 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 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. rESWT radial shock wave (RSW) transmits low- to medium-energy shockwaves radially over a larger surface area. Food and Drug Administration (FDA) approval was first granted in 2002 for focused ESWT devices and in 2007 for RSW devices.

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. 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 and tendinopathy syndromes. Common syndromes are summarized in Table 1. Many tendinitis and tendinopathy syndromes are related to overuse injury. Conservative treatment often involves rest, activity modifications, physical therapy, and anti-inflammatory medications.

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). We used the following criteria to define nonunion:

- 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.

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

ESWT has been investigated for various other musculoskeletal conditions, including medial tibial stress syndrome (MTSS), 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 a characteristic of upper motor neuron dysfunction, which may be due to a variety of pathologies.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Currently, 6 focused ESWT devices have been approved by the U.S. 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	Delivery System	Indication

	Date	Type	
OssaTron® device (HealthTronics, Marietta, GA)	2000	Electrohydraulic delivery system	• Chronic proximal plantar fasciitis, ie, pain persisting >6 mo and unresponsive to conservative management • Lateral epicondylitis
Epos™ Ultra (Dornier, Germering, Germany)	2002	Electromagnetic delivery system	Plantar fasciitis
Sonocur® Basic (Siemens, Erlangen, Germany)	2002	Electromagnetic delivery system	Chronic lateral epicondylitis (unresponsive to conservative therapy for >6 mo)
Orthospec™ Orthopedic ESWT (Medispec, Germantown, MD)	2005	Electrohydraulic spark-gap system	Chronic proximal plantar fasciitis in patients ≥18 y
Orbasone™ Pain Relief System (Orthometrix, White Plains, NY)	2005	High-energy sonic wave system	Chronic proximal plantar fasciitis in patients ≥18 y
Duolith® SD1 Shock Wave Therapy Device (Storz Medical AG, Switzerland)	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 May 2007, Dolorclast®‡ (EMS Electro Medical Systems; Nyon, Switzerland), 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.

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

It was informed by a 2001 TEC Assessment that concluded ESWT met TEC criteria as a treatment for plantar fasciitis in patients who had not responded to conservative therapies. A 2003 TEC Assessment reviewed the subsequent literature on ESWT for musculoskeletal conditions with a focus on 3 conditions: plantar fasciitis, tendinitis of the shoulder, and tendinitis of the elbow. The 2003 TEC Assessment came to different conclusions, specifically, that ESWT did not meet TEC criteria as a treatment of plantar fasciitis or

other musculoskeletal conditions. In 2004, updated TEC Assessments were completed for plantar fasciitis and tendinitis of the elbow. These Assessments concluded that ESWT did not meet TEC criteria for the treatment of these conditions.

The most clinically relevant outcome measures of ESWT used for musculoskeletal conditions are pain and functional limitations. Pain is a subjective, patient-reported measure. Therefore, pain outcomes require quantifiable pre- and posttreatment measures. Pain is most commonly measured with a visual analog scale (VAS). Quantifiable pre- and posttreatment measures of functional status are also used, such as 12-Item Short-Form Health Survey (SF-12) and SF-36. Minor adverse events of ESWT are common but transient, including local pain, discomfort, trauma, bleeding, and swelling. More serious adverse events of ESWT may potentially include neurologic damage causing numbness or tingling, permanent vascular damage, or rupture of a tendon or other soft tissue structure.

Because of the variable natural history of plantar fasciitis and other musculoskeletal conditions and the subjective nature of the outcome measures, randomized controlled trials (RCTs) are needed to determine whether outcomes are improved with ESWT. Trials should include a homogenous population of patients with a defined clinical condition, use standardized outcome measures whenever possible, and define a priori the magnitude of response that is clinically significant. The following is a summary of key studies to date.

ESWT FOR PLANTAR FASCIITIS

Systematic Reviews

Eight studies met the inclusion criteria for the 2004 TEC Assessment. Five double-blind RCTs, reporting on 992 patients, were considered high quality. Overall, evidence included in this Assessment showed a statistically significant effect on the between-group difference in morning pain measured on a 0-to-10 VAS score. Uncertain was the clinical significance of the change. The absolute value and effect size were small. Complete information on the number needed to treat to achieve 50% to 60% reduction in morning pain came from 2 studies of high-energy ESWT (and including confidential data provided by Dornier). The combined number needed to treat was 7 (95% confidence interval [CI], 4 to 15). Improvements in pain measures were not associated with improvements in function. Effect size for improvement in pain with activity was not significant, based on reporting for 81% of patients in all studies and 73% of patients in high-energy ESWT studies. Success in improvement in Roles and Maudsley score was reported for fewer than half the patients: although statistically significant, CIs were wide. Where reported, improvement in morning pain was not accompanied by a significant difference in quality of life measurement (SF-12 Physical and Mental Component Summary scores) or use in pain medication.

Two recent meta-analyses were published; each included 9 RCTs (8 of the 9 trials were in both meta-analyses). Both meta-analyses used the Cochrane risk of bias tool to assess the quality of the included RCTs. Results must be interpreted with caution due to the following limitations: lack of uniform measurement of outcomes, heterogeneity in ESWT protocols (focused and radial, the number of shocks per treatment, treatment duration), and lack of functional outcomes.

The meta-analysis by Sun et al (2017) evaluated the efficacy of all ESWT, then conducted subgroup analyses on the type of ESWT (focused shock wave [FSW], RSW). The literature search, conducted through July 2016, identified 9 trials for inclusion (total N=935 patients). An outcome in all 9 trials was "therapeutic success" rate, defined as a proportion of patients experiencing a decrease in VAS pain score from baseline more than a threshold of either at least 50% or at least 60%. Only 4 studies provided reduction in pain data (3 FSW, 1 RSW). Pooled results are summarized in Table 3.

A meta-analysis by Lou et al (2016) evaluated the efficacy of ESWT without local anesthesia in patients with recalcitrant plantar fasciitis. The literature search, conducted through September 2015, identified 9 trials for inclusion (N=1174). Meta-analyses focused on pain reduction at 12 weeks follow-up: overall, at first step in the morning, and during daily activities. Three RCTs also provided data to analyze improvement in the Roles and Maudsley score to excellent or good at 12-week follow-up. Analyses are summarized in Table 3.

Table 3. Summary of Meta-Analyses for the Use of ESWT for Plantar Fasciitis

Outcomes (Year)	No. of Trials	No. of Patients	Odds Ratio	95% CI	I^2, %
Sun et al (2017)					
Success rate, all ESWT	9	935	2.58	1.97 to 3.39	38
Success rate, FSW	6	474	2.17	1.49 to 3.16	0
Success rate, RSW	3	461	4.63	1.30 to 16.46	81
Pain reduction, all ESWT	4	559	1.01	-0.01 to 2.03	96
Pain reduction, FSW	3	315	1.29	0.39 to 2.19	87
Lou et al (2016)			**Relative Risk**		
Roles and Maudsley score improvement	3	529	1.51	1.26 to 1.81	0
Pain reduction, overall	5	773	1.50	1.27 to 1.77	0
Pain reduction, at first step in morning	4	617	1.32	1.11 to 1.56	0
Pain reduction, during daily activities	3	529	1.37	1.14 to 1.65	0

CI: confidence interval; ESWT: extracorporeal shock wave treatment; FSW: focused shock wave; RSW: radial shock wave.

A systematic review and meta-analysis by Yin et al (2014) evaluated 7 RCTs or quasi-RCTs of ESWT for chronic (≥6 months) recalcitrant plantar fasciitis. Treatment success rate of the 5 trials (n=448 patients) that evaluated low-intensity ESWT showed ESWT was more likely than the control treatment to be successful (pooled relative risk, 1.69; 95% CI, 1.37 to 2.07; p<0.001). In pooled analysis of 2 trials (n=105 subjects) that evaluated high-intensity ESWT, there was no difference between ESWT and control in treatment success. A strength of this analysis is restricting the population to patients with at least 6 months of symptoms because this clinical population is more difficult to treat and less likely to respond to interventions. However, a weakness is the heterogeneity in the definition of "treatment success" across the trials, which makes interpreting the pooled analysis challenging.

Meta-analyses of RCTs published in 2013 have reported that ESWT for plantar fasciitis is better than or comparable to placebo in reducing pain and improving functional status in the short-term. However, RCTs were subject to a number of limitations. They reported inconsistent results, and heterogeneity across them sometimes precluded meta-analysis of pooled data. Outcomes measured and study protocols (e.g., dose intensities, type of shockwaves, the frequency of treatments) also lacked uniformity. Also, given that plantar fasciitis often resolves within a 6-month period, we require longer follow-up studies to compare ESWT results with the natural resolution of the condition. The clinical significance of results reported at shorter follow-up, such as 3 months, is uncertain.

Randomized Controlled Trials

Trials With Sham Controls
We discuss several representative RCT trials included in the systematic reviews next.

Gollwitzer et al (2015) reported results of a sham-controlled randomized trial, with patients and outcome assessments blinded, evaluating ESWT for plantar fasciitis present for at least 6 months and refractory to at least 2 nonpharmacologic and 2 pharmacologic treatments. A total of 250 subjects were enrolled (126 in the ESWT group, 124 in the placebo group). The trial's primary outcome was an overall reduction of heel pain, measured by percentage change of the VAS composite score at 12 weeks. Median decrease for the ESWT group was -69.2% and -34.5% for the placebo group (effect size, 0.6026; p=0.003). Secondary outcomes included success rates defined as decreases in heel pain of at least 60% from baseline. Secondary outcomes generally favored the ESWT group. Most patients reported satisfaction with the procedure. Strengths of this trial included intention-to-treat analysis, use of validated outcome measures, and at least some reporting of changes in success rates (rather than percent decrease in pain) for groups. There was some potential for bias because treating physicians were unblinded.

In 2005, results were reported from the U.S. FDA–regulated trials delivering ESWT with the Orthospec and Orbasone Pain Relief System. In the RCT evaluating Orthospec, investigators conducted a multicenter, double-blind, sham-controlled trial randomizing 172 participants with chronic proximal plantar fasciitis failing conservative therapy to ESWT or to sham treatments. At 3 months, the ESWT arm had lower investigator-assessed pain levels with the application of a pressure sensor (0.94 points lower on a 10-point VAS; 95% CI, 0.02 to 1.87). However, this improvement was not found for patient-assessed activity and function. In the trial supporting the FDA approval of Orbasone, investigators conducted a multicenter, randomized, sham-controlled, double-blind trial evaluating 179 participants with chronic proximal plantar fasciitis. At 3 months, both active and sham groups improved in patient-assessed pain levels on awakening (by 4.6 and 2.3 points, respectively, on a 10-point VAS; absolute difference between groups, 2.3; 95% CI, 1.5 to 3.3). While ESWT was associated with more rapid and statistically significant improvement in a mixed-effects regression model, insufficient details were provided to evaluate the analyses.

Gerdesmeyer et al (2008) reported a multicenter, double-blind RCT of RSW conducted for FDA premarket approval of the Dolorclast. The trial randomized 252 patients, 129 to RSW and 122 to sham treatment. Patients had heel pain for at least 6 months and had failed at least 2 nonpharmacologic and 2

pharmacologic treatments. Over 90% of patients were compliant with the 3 weekly treatment schedule. Outcome measures were composite heel pain (pain on first steps of the day, with activity and as measured with Dolormeter), change in VAS score, and Roles and Maudsley score measured at 12 weeks and 12 months. Success was defined as a reduction of 60% or more in 2 of 3 VAS scores, or patient ability to work and complete activities of daily living, treatment satisfaction, and requiring no further treatment. Secondary outcomes at 12 weeks included changes in Roles and Maudsley score, SF-36 Physical Component Summary score, SF-36 Mental Component Summary score, investigator's and patient's judgment of effectiveness, and patient recommendation of therapy to a friend. At 12-week follow-up, RSW resulted in a decrease of the composite VAS score by 72.1% versus 44.7% after placebo (p=0.022). Success rates for the composite heel pain score were 61% and 42% (p=0.002). Statistically significant differences were noted on all secondary measures. A number of limitations prevent definite conclusions from being reached: the limited data on specific outcomes (e.g., presenting percent changes rather than actual results of measures); inadequate description of prior treatments; use of a composite outcome measure; no data on the use of rescue medication; and uncertainty in the clinical significance of changes in outcome measures.

Several smaller trials (≤50 patients) have shown inconsistent results.

Trials With Active Comparators
Eslamian et al (2016) published an RCT comparing RSW with corticosteroid injection for the treatment of plantar fasciitis. Patients were randomized to five 15-minute treatments of RSW at 3-day intervals (n=20) or to a single corticosteroid injection (n=20). Outcomes included VAS pain score (range, 0-10), satisfaction scale (range, 1-4), and a modified Foot Function Index consisting of self-reported items on pain and disability. After 2 months of follow-up, both groups reported significant improvements in all outcomes. Patients in the ESWT group reported higher patient satisfaction and larger improvements in Foot Function Index, but the differences between groups were not statistically significant.

Radwan et al (2012) compared ESWT with endoscopic plantar fasciotomy in 65 patients with refractory plantar fasciitis who had failed at least 3 lines of treatment in the preceding 6 months. Outcome measures included a 0-to-100 VAS assessing morning pain, the American Orthopaedic Foot and Ankle (AOFAS) Ankle-Hindfoot Scale score, and patient subjective assessment using the 4-item Roles and Maudsley score. Improvements were similar between the 2 treatment groups at the 1-year follow-up; however, a larger proportion of patients in the surgery group continued to report success at years 2 and 3 compared with those of the ESWT group.

Nonrandomized Studies
Nonrandomized studies have reported outcomes after ESWT for plantar fasciitis, but given the availability of randomized trials, such studies do not provide additional evidence on ESWT's efficacy compared with alternatives.

Section Summary: ESWT for Plantar Fasciitis
We identified numerous RCTs, including several well-designed double-blinded RCTs, that evaluated ESWT for the treatment of plantar fasciitis. Two systematic reviews and meta-analyses, including 9 RCTs each,

have been conducted. While 8 of 9 of the same trials were included in each meta-analysis, pooled results were inconsistent. One meta-analysis reported that ESWT reduced pain, while another reported nonsignificant pain reductions. Reasons for the differing results included 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). In studies reporting a benefit, the magnitude of effect for some or all outcomes was of uncertain clinical significance. Definitive, clinically meaningful treatment benefits at 3 months are not apparent, nor is it evident that the longer term disease natural history is altered with ESWT. Currently, it is not possible to determine whether ESWT improves outcomes for patients with plantar fasciitis.

ESWT FOR LATERAL EPICONDYLITIS

Systematic Reviews
Six randomized, double-blinded, placebo-controlled trials enrolling 808 patients with lateral epicondylitis (tendinitis of the elbow) met the inclusion criteria for the 2004 TEC Assessment. Four trials were rated good quality and are summarized next. Three trials used low-energy ESWT and one used high-energy ESWT. Two trials reported positive effects on pain, 1 trial had mixed results, and another large sham-controlled study reported negative results with ESWT.

- In the Sonocur trial (2002), 114 patients were randomized to low-energy ESWT or sham ESWT for 3 treatment sessions administered at 1-week intervals. The main outcome measures were percent response on a self-reported pain scale (at least 50% improvement on 0-to-100 VAS) and change in Upper Extremity Function Scale (UEFS) scores. Results of the 2 main outcome measures at 3 months showed greater improvement in the ESWT group. The response rate was 60% in the active treatment group and 29% in the placebo group ($p<0.001$). UEFS score improved by 51% in the active treatment group and by 30% in the placebo group ($p<0.05$).
- Rompe et al (2004) randomized 78 tennis players to 3 treatments at weekly intervals of low-energy or sham ESWT. Outcomes included pain ratings during wrist extension and Thomsen Provocation Test score, Roles and Maudsley score, UEFS score, grip strength, and satisfaction with return to activities. At the 3-month follow-up, the ESWT group significantly improved on all outcomes except grip strength compared with placebo. Treatment success (at least a 50% decrease in pain) was 65% for the ESWT group and 28% for the placebo group ($p<0.01$), and 65% of the ESWT group, compared with 35% of the placebo group, expressed satisfaction with their return to activities ($p=0.01$).
- The OssaTron trial (2000) randomized 183 patients to a single session of high-energy or sham ESWT. Treatment success was a 50% improvement on investigator- and patient-assessed pain using a 0-to-10 VAS and no or rare use of pain medication. At the 8-week follow-up, the ESWT group had a greater rate of treatment success (35%) than the placebo group (22%; $p<0.05$). The main driver for group differences in treatment success was the investigator-assessed pain (48% vs 29%, respectively; $p<0.01$); self-assessment of pain (81% vs 70%, respectively; $p=0.06$) and nonuse of pain medication (81% vs 70%, respectively; $p=0.09$) improved only marginally.

- Haake et al (2002) randomized 272 patients to 3 sessions of low-energy or sham ESWT. Treatment success was defined as achieving a Roles and Maudsley score of 1 or 2 with no need for additional treatments. At 12 weeks, the ESWT success rate was 25.8% and the placebo success rate was 25.4%. The percentage of Roles and Maudsley scores below 3 did not differ between groups at either the 12-week (31.7% ESWT vs 33.1% placebo) or 1-year (65.7% ESWT vs 65.3% placebo) follow-ups. Moreover, the groups did not differ on any of 5 pain assessment measures or on grip strength.

Other systematic reviews published since the 2004 Assessment have reached similar conclusions. A 2005 Cochrane review concluded, "there is 'Platinum' level evidence [the strongest level of evidence] that shock wave therapy provides little or no benefit regarding pain and function in lateral elbow pain." A 2014 systematic review of electrophysical therapies for epicondylitis found conflicting evidence on the short-term benefits of ESWT. No evidence demonstrated any long-term benefits with ESWT over placebo for epicondylitis treatment.

Randomized Controlled Trials
Several small RCTs on ESWT for lateral epicondylitis have been published since the 2004 TEC Assessment.

Yang et al (2017) published results from an RCT (N=30) comparing RSW plus physical therapy with physical therapy alone in patients with lateral epicondylitis. Outcomes include VAS pain and grip strength. Significant differences were seen in grip strength by 12 weeks of follow-up; the mean difference in grip strength between groups was 7.7 (95% CI, 1.3 to 14.2), favoring RSW. Significant differences in VAS pain (10-point scale) were not detected until 24 weeks of follow-up; mean difference between groups was -1.8 (95% CI, -3.0 to -0.5), favoring RSW.

A small RCT by Capan et al (2016) comparing RSW (n=28) or sham RSW (n=28) for lateral epicondylitis did not find significant differences between groups in grip strength or function. However, this trial might have been underpowered to detect a difference.

Lizis (2015) compared ESWT with therapeutic ultrasound among 50 patients with chronic tennis elbow. For most pain measures assessed, pain was lower in the ESWT group immediately posttreatment and at 3 months, except pain on gripping, which was higher in the ESWT group. While trial results favored ESWT, it had a high risk of bias, in particular, due to lack of blinding of participants and outcome assessors, which would make interpretation of results difficult.

Gunduz et al (2012) compared ESWT with 2 active comparators. This trial randomized 59 patients with lateral epicondylitis to ESWT, physical therapy, or a single corticosteroid injection. Outcome measures were VAS pain, grip strength, and pinch strength by dynamometer. The authors reported that VAS pain scores improved significantly in all 3 groups at the -month follow-up, but reported no between-group differences. No consistent changes were reported for grip strength or on ultrasonography.

Staples et al (2008) reported a double-blind controlled trial of ultrasound-guided ESWT for epicondylitis in 68 patients. Patients were randomized to 3 ESWT treatments or 3 treatments at a subtherapeutic dose at weekly intervals. There were significant improvements in most of the 7 outcome measures for both groups over 6 months of follow-up but no between-group differences. The authors found little evidence to support the use of ESWT for this indication.

Pettrone and McCall (2005) reported results from a multicenter, double-blind, randomized trial of 114 patients receiving either ESWT in a "focused" manner (2000 impulses at 0.06 mJ/mm^2 without local anesthesia) weekly for 3 weeks or placebo. Patients were followed for 12 weeks, and benefit demonstrated with the following outcomes: VAS pain (0-10 points) declined at 12 weeks in the treatment group from 7.4 to 3.8; among placebo patients, from 7.6 to 5.1. A reduction in pain on the Thomsen Provocation Test of at least 50% was demonstrated in 61% of those treated compared with 29% in the placebo group. Mean improvement on a 10-point UEFS activity score was 2.4 for ESWT-treated patients compared with 1.4 in the placebo group—a difference at 12 weeks of 0.9 (95% CI, 0.18 to 1.6). Although this trial found a benefit of ESWT for lateral epicondylitis over 12 weeks, the placebo group also improved significantly; whether the natural history of disease was altered with ESWT is unclear.

Nonrandomized Studies
Nonrandomized observational studies have reported functional outcomes after ESWT for epicondylitis; however, these studies provide limited evidence on the effectiveness of ESWT for lateral epicondylitis compared with other therapies.

Section Summary: ESWT for Lateral Epicondylitis
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. The highest quality trials tend to show no benefit, and systematic reviews have generally concluded that the evidence does not support a treatment benefit.

ESWT FOR SHOULDER TENDINOPATHY
Numerous small RCTs have evaluated ESWT for shoulder tendinopathy, primarily calcific, and noncalcific tendinopathy of the rotator cuff. Several systematic reviews are discussed below, along with RCTs published after the last systematic review's literature search cutoff point.

Systematic Reviews
A systematic review and network meta-analysis of RCTs by Wu et al (2017) compared the effectiveness of nonoperative treatments for chronic calcific tendinitis. The literature review, conducted through April 2016, identified 14 RCTs (total N=1105 patients) for inclusion. Treatments included in the network meta-analysis were ultrasound-guided needling (UGN), RSW, high-energy FSW (H-FSW), low-energy FSW (L-FSW), ultrasound therapy, and transcutaneous electrical nerve stimulation. Trials either compared the treatments with each other or with sham/placebo. Outcomes were pain (VAS range, 0 [no pain] to 10 [worst pain]), functional assessment (Constant-Murley Score [CMS], up to 100 [asymptomatic]), and calcific deposit change ("no change," "partial resolution," or "complete resolution," assessed by radiograph or ultrasound).

Treatments most effective in reducing pain and resolving calcific deposits were UGN, RSW, H-FSW. The only treatment significantly improving function was H-FSW. Table 4 lists the treatments, from most effective to the least effective, by outcome, as determined by network meta-analysis.

Table 4. Ranking of Nonoperative Treatments for Chronic Calcific Tendinitis, by Outcome

Pain Reduction (8 Trials)		Functional Assessment (7 Trials)		Calcific Deposit Change	
Treatment	**Difference From Control (95% CrI)**	**Treatment**	**Difference From Control (95% CrI)**	**Treatment**	**Difference From Control (95% CrI)**
UGN	8.0 (4.9 to 11.1)	H-FSW	25.1 (10.3 to 40.0)	UGN	6.8 (3.8 to 9.9)
RSW	6.1 (3.9 to 8.3)	TENS	8.7 (-13.5 to 30.9)	RSW	6.2 (3.2 to 9.1)
H-FSW	4.2 (2.0 to 6.4)	L-FSW	7.6 (-7.2 to 22.5)	H-FSW	2.4 (1.5 to 3.4)
TENS	3.2 (-0.1 to 6.5)	Ultrasound	3.3 (-15.0 to 21.6)	Ultrasound	2.1 (0.4 to 3.8)
L-FSW	1.9 (-0.4 to 4.3)			TENS	1.9 (-0.8 to 4.6)
Ultrasound	1.1 (-1.7 to 3.9)			L-FSW	1.2 (0.1 to 2.2)

CrI: credible interval; H-FSW: high-energy focused extracorporeal shockwave; L-FSW: low-energy focused extracorporeal shockwave; RSW: radial extracorporeal shockwave; TENS: transcutaneous electrical nerve stimulation; UGN: ultrasound-guided needling.

A systematic review and network meta-analysis of RCTs by Arirachakaran et al (2017) evaluated ESWT, ultrasound-guided percutaneous lavage (UGPL), subacromial corticosteroid injection (SAI), and combined treatments for rotator cuff calcific tendinopathy. The literature search, conducted through September 2015, identified 7 RCTs for inclusion. Six of the trials had ESWT as 1 treatment arm, with the following comparators: placebo (4 trials), UGPL plus ESWT (1 trial), and UGPL plus SAI (1 trial). One trial compared UGPL plus SAI with SAI alone. Outcomes were CMS (5 trials), VAS pain (5 trials), and size of calcium deposit (4 trials). Network meta-analysis results are summarized below:

- VAS pain:
  - ESWT, UGPL plus SAI, and SAI alone were more effective in reducing pain than placebo
  - Compared with each other, ESWT, UGPL plus SAI, and SAI alone did not differ statistically
- CMS:
  - ESWT was statistically more effective than placebo
  - No other treatment comparisons differed statistically
- Size of calcium deposit:
  - UGPL plus SAI was statistically more effective than placebo and SAI alone
  - ESWT was statistically better than SAI alone, but not more effective than placebo.

In a systematic review by Yu et al (2015) of RCTs of various passive physical modalities for shoulder pain, which included 11 studies considered at low risk of bias, 5 studies reported on ESWT. Three, published from 2003 to 2011, assessed calcific shoulder tendinopathy, including 1 RCT comparing high-energy ESWT with low-energy ESWT (N=80), 1 RCT comparing RSW with sham ESWT (N=90), and 1 RCT comparing high-energy ESWT with low-energy ESWT and sham ESWT (N=144). All 3 trials reported statistically significant differences between groups for change in VAS score for shoulder pain.

Bannuru et al (2014) published a systematic review of RCTs comparing high-energy ESWT with placebo or low-energy ESWT for the treatment of calcific or noncalcific shoulder tendinitis. All 7 studies comparing ESWT with placebo for calcific tendinitis reported significant improvements in pain or functional outcomes associated with ESWT. Only high-energy ESWT was consistently associated with significant improvements in both pain and functional outcomes. Eight studies comparing high- with low-energy ESWT for calcific tendinitis did not demonstrate significant improvements in pain outcomes, although shoulder function improved. Trials were reported to be of low quality with a high risk of bias.

In another meta-analysis of RCTs comparing high-energy with low-energy ESWT, Verstraelen et al (2014) evaluated 5 studies (total N=359 patients) on calcific shoulder tendinitis. Three were considered high quality. High-energy ESWT was associated with significant improvements in functional outcomes, with a mean difference at 3 months of 9.88 (95% CI, 0.04 to 10.72; p<0.001). High-energy ESWT was more likely to lead to resolution of calcium deposits at 3 months (pooled OR=3.4; 95% CI, 1.35 to 8.58; p=0.009). Pooled analysis could not be performed for 6-month follow-up data.

In a 2013 systematic review and meta-analysis, Ioppolo et al identified 6 RCTs that compared ESWT with sham treatment or placebo for calcific shoulder tendinopathy. Greater shoulder function and pain improvements were reported at 6 months with ESWT than placebo. Most studies were considered low quality.

Huisstede et al published a systematic review of RCTs in 2011 that included 17 RCTs on calcific (n=11) and noncalcific (n=6) tendinopathy of the rotator cuff. Moderate-quality evidence was found for the efficacy of ESWT versus placebo for calcific tendinopathy, but not for noncalcific tendinopathy. High-frequency ESWT was found to be more efficacious than low-frequency ESWT for calcific tendinopathy.

Randomized Clinical Trials
An RCT by Carlisi et al (2016) assessed the use of ESWT combined with supervised eccentric training for the treatment of shoulder tendinopathy. In this pilot study, 22 patients were randomized to focused ESWT or to focused ESWT plus supervised eccentric training. After 9 weeks of follow-up, both groups showed statistically significant improvements in shoulder pain and upper-limb function, but no between-group differences. Lack of a comparison group without ESWT limits the utility of these results.

An RCT by Kim et al (2016) evaluated the use of ESWT in patients with calcific tendinitis. All patients received nonsteroidal anti-inflammatory drugs, transcutaneous electrical nerve stimulation, and ultrasound therapy (N=34). A subset (n=18) also received ESWT, 3 times a week for 6 weeks. CMS was measured at 2, 6, and 12 weeks. Both groups improved significantly from baseline. The group receiving ESWT improved significantly more than the control group; however, the lack of sham control limits interpretability of results.
An RCT by Santamato et al (2016) randomized 30 patients to ESWT plus isokinetic exercise (n=15) or to ESWT alone (n=15) for the treatment of subacromial impingement syndrome. Focused ESWT was administered 3 times at 3-day intervals. Outcomes were VAS pain and CMS. After 2 months of follow-up, both groups showed statistically significant improvements in pain and CMS compared with baseline. The

improvements experienced by the combined group were significantly larger than those experienced by the ESWT alone group. Lack of a comparison group without ESWT limits utility of these results.

The following are select trials included in the systematic reviews.

Kim et al (2014) compared UGPL plus SAI with ESWT in patients with unilateral calcific shoulder tendinopathy and ultrasound-documented calcifications of the supraspinatus tendon. Sixty-two patients were randomized. Fifty-four patients were included in the data analysis (8 subjects were lost to follow-up). ESWT was performed for 3 sessions once weekly. Radiologic evaluation was blinded, although it was not specified whether evaluators for pain and functional outcomes were blinded. After an average follow-up of 23.0 months (range, 12.1-28.5 months), functional outcomes improved in both groups: for the UGPL plus SAI group, scores on the American Shoulder and Elbow Surgeons scale improved from 41.5 to 91.1 (p=0.001) and on the Simple Shoulder Test from 38.2% to 91.7% (p=0.03). In the ESWT group, scores on the American Shoulder and Elbow Surgeons scale improved from 49.9 to 78.3 (p=0.026) and on the Simple Shoulder Test from 34.0% to 78.6% (p=0.017). Similarly, VAS pain scores improved from baseline to the last follow-up in both groups. At the last follow-up visit, calcium deposit size was smaller in the UGPL plus SAI group (0.5 mm) than in the ESWT group (5.6 mm; p=0.001).

An example of a high-energy versus low-energy trial is that by Schofer et al (2009), which assessed 40 patients with rotator cuff tendinopathy. An increase in function and reduction of pain were found in both groups (p<0.001). Although improvement in the Constant score was greater in the high-energy group, there were no statistically significant differences in any outcomes studied (Constant score, pain, subjective improvement) at 12 weeks or 1 year posttreatment.

At least 1 RCT (2012) has evaluated patients with bicipital tendinitis of the shoulder. This trial randomized 79 patients with tenosynovitis to ESWT or to sham treatment. ESWT was given for 4 sessions over 4 weeks. Outcomes were measured at up to 12 months using a VAS for pain and the L'Insalata Shoulder Questionnaire. The mean decrease in the VAS score at 12 months was greater for the ESWT group (4.24 units) than with sham treatment (0.47 units; p<0.001). There were similar improvements in the L'Insalata Shoulder Questionnaire, with an improvement in scores for the ESWT group of 22.8 points.

Section Summary: ESWT for Shoulder Tendinopathy
A number of small RCTs, summarized in several systematic reviews and meta-analyses, have evaluated the use of ESWT to treat shoulder tendinopathy. A network meta-analyses focused on 3 outcomes: pain reduction, functional assessment, and change in calcific deposits. One network meta-analysis separated trials using H-FSW, L-FSW, and 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 regarding 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.

ESWT FOR ACHILLES TENDINOPATHY
Evidence for the use of ESWT for Achilles tendinopathy consists of systematic reviews, an RCT published after the reviews, and nonrandomized studies.

Systematic Reviews
Mani-Babu et al (2015) reported results of a systematic review of studies evaluating ESWT for lower-limb tendinopathies. The review included 20 studies, 11 of which evaluated ESWT for Achilles tendinopathy (5 RCTs, 4 cohort studies, 2 case-control studies). In pooled analysis, reviewers reported that evidence was limited, but showed that ESWT was associated with greater short-term (<12 months) and long-term (>12 months) improvements in pain and function compared with nonoperative treatments, including rest, footwear modifications, anti-inflammatory medication, and gastrocnemius-soleus stretching and strengthening. Reviewers noted that findings from RCTs of ESWT for Achilles tendinopathy were contradictory, but that some evidence supported short-term improvements in function with ESWT. Reviewers warned that results be interpreted with caution due to the heterogeneity in patient populations (age, insertional vs mid-portion Achilles tendinopathy) and treatment protocols.

Al-Abbad and Simon (2013) conducted a systematic review of 6 studies on ESWT for Achilles tendinopathy. Selected for the review were 4 small RCTs and 2 cohort studies. Satisfactory evidence was found in 4 studies demonstrating the effectiveness of ESWT in the treatment of Achilles tendinopathy at 3 months. However, 2 RCTs found no significant difference between ESWT and placebo in the treatment of Achilles tendinopathy. These trials are described next.

Randomized Controlled Trials
Lynen et al (2017) published results from an RCT comparing 2 peri-tendinous hyaluronan injections (n=29) with 3 ESWT applications (n=30) for the treatment of Achilles tendinopathy. The primary outcome was percent change in VAS pain at the 3-month follow-up. Other measurements included the Victorian Institute of Sports Assessment–Achilles (VISA-A), clinical parameters (redness, warmth, swelling, tenderness, edema), and patients' and investigators' impression of treatment outcome. Follow-up was conducted at 4 weeks, 3 months, and 6 months. Pain decreased in both groups from baseline, though percent decrease in pain was statistically larger in the hyaluronan injections group than in the ESWT group at all follow-up time points. Secondary outcomes also showed larger improvements in the hyaluronan injections group.

The 2 trials described below were included in the systematic reviews.

Rasmussen et al (2008) reported on a single-center, double-blind controlled trial with 48 patients, half randomized after 4 weeks of conservative treatment to 4 sessions of active RSW and half to sham ESWT. The primary end point was AOFAS score measuring function, pain, and alignment and VAS pain score. AOFAS score after treatment increased from 70 to 88 in the ESWT group and from 74 to 81 in the control (p=0.05). Pain was reduced in both groups, with no statistically significant difference between groups. The authors suggested that the AOFAS might not be appropriate to evaluate treatment of Achilles tendinopathy.

Costa et al (2005) reported on a randomized, double-blind, placebo-controlled trial of ESWT for chronic Achilles tendon pain treated monthly for 3 months. The trial randomized 49 participants and was powered to detect a 50% reduction in VAS pain scores. No differences in pain relief at rest or during sports participation were found at 1 year. Two older ESWT-treated participants experienced tendon ruptures.

Nonrandomized Studies
Lee et al (2017) studied factors that affect immediate (1 week after last treatment) and long-term (mean 26 months after last treatment) success of ESWT for chronic refractory Achilles tendinopathy. Patients with "poor" or "fair"' grades on Roles and Maudsley assessment after conservative treatment for Achilles tendinopathy (N=33 patients, 45 feet) were treated weekly with ESWT to a maximum of 12 sessions. Success was defined as Roles and Maudsley scores of "good" or "excellent." Thirty-two (71%) feet were considered successfully treated at the long-term follow-up assessment. Factors predicting immediate success included retrocalcaneal enthesophyte on x-ray, the presence of abnormal ultrasonography echogenicity, and shorter duration of soreness after first ESWT. The only factor predicting long-term success was shorter duration of soreness after first ESWT.

Wu et al (2016) compared the effect of ESWT on insertional Achilles tendinopathy with or without Haglund deformity. A total of 67 patients were enrolled, 30 with and 37 without the deformity. Patients received weekly ESWT for 5 weeks. The VISA-A scores improved significantly in both groups, regardless of the presence or absence of the deformity.

Section Summary: ESWT for Achilles Tendinopathy
Two systematic reviews of RCTs and nonrandomized studies have evaluated the use of ESWT for Achilles tendinopathy. In the most recent systematic review (2015), a pooled analysis found that ESWT reduced both short- and long-term pain compared with nonoperative treatments, although the authors 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 significantly higher in the injection group.

ESWT FOR PATELLAR TENDINOPATHY
Evidence for the use of ESWT for patellar tendinopathy consists of systematic reviews, an RCT published after the reviews, and a nonrandomized study.

Systematic Reviews
Van Leeuwen et al (2009) conducted a literature review to study the effectiveness of ESWT for patellar tendinopathy and to draft a treatment protocol. Reviewers found that most studies of the 7 selected studies had methodologic deficiencies, small numbers and/or short follow-up periods, and variation in treatment parameters. They concluded ESWT appeared to be a safe and promising treatment but could not recommend a treatment protocol. In a 2014 RCT of patients with chronic patellar tendinopathy (N=46), despite at least 12 weeks of nonsurgical management, improvements in pain and functional outcomes were

significantly greater ($p<0.05$) with plasma-rich protein injections than with ESWT at 6 and 12 months, respectively.

In the systematic review of ESWT for lower-extremity tendinopathies (previously described), Mani-Babu et al (2015) identified 7 studies of ESWT for patellar tendinopathy (2 RCTs, 1 quasi-RCT, 1 retrospective cross-sectional study, 2 prospective cohort studies, 1 case-control study). The 2 RCTs came to different conclusions: one found no difference in outcomes between ESWT and placebo at 1, 12, or 22 weeks, whereas the other found improved outcomes on vertical jump test and Victorian Institute of Sport Assessment–Patellar (VISA-P) scores at 12 weeks with ESWT compared with placebo. Two studies that evaluated outcomes beyond 24 months found ESWT comparable to patellar tenotomy surgery and better than nonoperative treatments.

Randomized Controlled Trials
An RCT by Thijs et al (2017) compared the use of ESWT plus eccentric training (n=22) with sham shock wave therapy plus eccentric training (n=30) for the treatment of patellar tendinopathy. Patients were physically active with a mean age 28.6 years (range, 18-45 years). ESWT and sham shock wave were administered in 3 sessions, once weekly. Patients were instructed to perform eccentric exercises, 3 sets of 15 repetitions twice daily for 3 months on a decline board at home. Primary outcomes were VISA-P score and pain score during functional knee loading tests (10 decline squats, 3 single leg jumps, 3 vertical jumps). Measurements were taken at baseline, 6, 12, and 24 weeks. There were no statistically significant differences between the ESWT and sham shock wave groups for any of the primary outcome measurements at any follow-up except for the vertical jump test at week 6.

Nonrandomized Studies
Williams et al (2017) investigated whether the location of the patellar tendinopathy impacted the response to ESWT. All 40 patients underwent a magnetic resonance imaging scan. The scan showed that 20 patients had tendon involvement and 20 patients had retropatella fat pad extension. All patients underwent RSW. If there was no improvement of symptoms following RSW, patients were then offered arthroscopic débridement. Seventeen of the 20 patients with tendon involvement responded to the RSW and needed no further treatment. None of the patients with retropatella fat extension responded to RSW.

Section Summary: ESWT for Patellar Tendinopathy
The trials on use of ESWT for patellar tendinopathy have reported inconsistent results and were heterogeneous in treatment protocols and lengths of follow-up. One nonrandomized study has suggested that the location of the patellar tendinopathy might impact the response to ESWT.

ESWT FOR MEDIAL TIBIAL STRESS SYNDROME
Newman et al (2017) published a double-blind, sham-controlled randomized trial on the use of ESWT for the treatment of 28 patients with MTSS; commonly called shin splints. Enrolled patients had running-related pain for at least 21 days confined to the posteromedial tibia, lasting for hours or days after running. Patients received treatments (ESWT or sham) at weeks 1, 2, 3, 5, and 9 and patients were instructed to keep activity levels as consistent as possible. At week 10 measurements, there was no difference between the treatment

and control groups in self-reported pain during bone pressure, muscle pressure, or during running. There was no difference in pain-limited running distances between groups.

Rompe et al (2010) published a report on the use of ESWT in MTSS. In this nonrandomized cohort study, 47 patients with MTSS for at least 6 months received 3 weekly sessions of RSW and were compared with 47 age-matched controls at 4 months. Mild adverse events were noted in 10 patients: skin reddening in 2 patients and pain during the procedure in 8 patients. Patients rated their condition on a 6-point Likert scale. Successful treatment was defined as self-rating "completely recovered" or "much improved." The authors reported a success rate of 64% (30/47) in the treatment group compared with 30% (14/47) in the control group. In a comment, Barnes raised several limitations of this nonrandomized study, including the possibility of selection bias.

Section Summary: ESWT for Medial Tibial Stress Syndrome
Evidence for the use of ESWT for MTSS includes a small RCT and a small nonrandomized study. The RCT showed no differences in self-reported pain measurements between study groups. The nonrandomized trial reported improvements with ESWT, but selection bias limits the strength of the conclusions.

ESWT FOR OSTEONECROSIS OF THE FEMORAL HEAD
A systematic review by Zhang et al (2016) evaluated evidence on the use of ESWT for osteonecrosis of the femoral head. The literature search, conducted through July 2016, identified 17 studies for inclusion (9 open-label studies, 4 RCTs, 2 cohort studies, 2 case reports). Study quality was assessed using the Oxford Centre of Evidence-Based Medicine Levels of Evidence (I = highest quality and V = lowest quality, and each level can be subdivided a through c). Four studies were Ib, 2 studies were IIb, and 11 studies were IV. Most studies included patients with Association Research Circulation Osseous categories I through III (out of 5 stages of osteonecrosis). Outcomes in most studies were VAS pain and Harris Hip Score. Reviewers concluded that ESWT can be a safe and effective method to improve motor function and relieve pain, particularly in patients with early-stage osteonecrosis. Studies that included imaging results showed that bone marrow edema could be relieved, but that necrotic bone were not reversed. Limitations on the evidence included the heterogeneity of treatment protocol (number of sessions, energy intensity, and focus size differed among studies) and the majority of studies were of low quality.

A systematic review of ESWT for osteonecrosis (avascular necrosis) of the femoral head was conducted by Alves et al in 2009. The literature search conducted through 2009 identified 5 articles, all from non-U.S. sites (2 RCTs, 1 comparative study, 1 open-label study, 1 case report; total N=133 patients). Several studies were from a single center in Taiwan. Of the 2 RCTs, one randomized 48 patients to the use of concomitant alendronate; both arms received ESWT treatments we and therefore ESWT was not a comparator. The other RCT compared ESWT with a standard surgical procedure. All results noted a reduction in pain during the trial, which the authors attributed to ESWT. However, reviewers, when discussing the limitations of the available evidence, noted a lack of double-blind designs, small numbers of patients enrolled, short follow-up times, and nonstandard interventions (e.g., energy level, the number of treatments).

An example of a comparative study included in the Zhang review was published by Chen et al (2009). In this study of 17 patients with bilateral hip osteonecrosis, 1 hip was treated with total hip arthroplasty while the other was treated with ESWT. Each patient was evaluated at baseline and after treatment using VAS for pain and Harris Hip Score, a composite measure of pain and hip function. There was a significant reduction in scores before and after both treatments. Hips treated with ESWT were also evaluated for radiographic reduction of bone marrow edema on magnetic resonance imaging, which also appeared to be reduced. A comparison of ESWT data with total hip arthroplasty data showed the magnitude of improvement was greater for the ESWT-treated hips. However, treatment allocations were not randomized. The hip with the greater degree of disease was treated with surgery in each case. Moreover, the time between hip interventions within the same patient averaged 17.3 months (range, 6-36 months); in all but 1 case, surgery preceded ESWT. Conclusions about the superiority of either intervention cannot be made.

Han et al (2016) evaluated the effect of 2 energy intensities of ESWT on early-stage (the Association Research Circulation Osseous categories I through III) osteonecrosis of the femoral head. One arm of the trial (n=15) received 1000 shocks per session with an energy flux density of 0.12 mJ/mm^2 and the other arm (n=15) received 1000 shocks per session with an energy flux density of 0.32 mJ/mm^2. Outcomes included VAS pain and Harris Hip Score; they were measured at baseline, and at 1, 3, and 6 months. Pain significantly decreased and hip functional scores significantly increased in both treatment groups at each follow-up measurement. The authors concluded that lower energy levels of ESWT might be effective in treating early-stage osteonecrosis of the femoral head.

Section Summary: ESWT for Osteonecrosis of the Femoral Head
The body of evidence on the use of ESWT for osteonecrosis of the femoral head consists of 2 systematic reviews of small, mostly nonrandomized studies. Many of the studies are low quality and lacked comparators. While most studies reported favorable outcomes with ESWT, limitations such as the heterogeneity in the treatment protocols, patient populations, and lengths of follow-up make conclusions on the efficacy of ESWT for osteonecrosis uncertain.

ESWT FOR NONUNION OR DELAYED UNION OF ACUTE FRACTURE
The evidence for the use of ESWT for nonunion or delayed union fractures consists of a systematic review of an RCT and case series, and 2 RCTs published after the review.

Systematic Reviews
Zelle et al (2010) published a review of the English and German medical literature on ESWT for the treatment of fractures and delayed union/nonunion. Limiting the review to studies with more than 10 patients, reviewers identified 10 case series and 1 RCT. The number of treatment sessions, energy levels, and definitions of nonunion varied across studies; union rate after the intervention was likewise defined heterogeneously, ranging from 40.7% to 87.5%. Reviewers concluded the overall quality of evidence was conflicting and of poor quality.

Randomized Clinical Trials
The RCT in the Zelle review reported on the use of ESWT in acute long bone fractures. Wang et al (2007) randomized 56 trauma patients with femur or tibia fractures to a single ESWT treatment following surgical fixation while still under anesthesia. Patients in the control group underwent surgical fixation but did not receive the ESWT. Patients were evaluated for pain and percent weight-bearing capability by an independent, blinded evaluator at 3, 6, and 12 months. Radiographs taken at these same intervals were evaluated by a radiologist blinded to study group assignment. Both groups showed significant improvement in pain scores and weight-bearing status. Between-group comparisons of pain by VAS and weight bearing favored ESWT patients at each interval. At 6 months, patients who had received ESWT had VAS scores of 1.2 compared with 2.5 in the control group ($p<0.001$); mean percentage of weight bearing at 6 months was 87% and 78%, respectively ($p=0.01$). Radiographic evidence of union at each interval also favored the ESWT group. At 6 months, 63% (17/27) of the treatment group achieved fracture union compared with 20% (6/30) in the control group ($p<0.001$). The authors noted some limitations of the trial: the small number of patients enrolled, surgeries performed by multiple surgeons, and questions about the adequacy of randomization.

Randomized clinical trials published after the review are described below.

In a multicenter RCT, Cacchio et al (2009) randomized 126 patients to 3 groups: low-energy ESWT, high-energy ESWT therapy, or surgery. Nonunion fractures were defined as at least 6 months without evidence of radiographic healing. The primary end point was radiographic evidence of healing. Secondary end points were pain and functional status, collected by blinded evaluators. Neither patients nor treating physicians were blinded. At 6 months, healing rates in the low-energy ESWT, high-energy ESWT, and surgical arms were similar (70%, 71%, 73%, respectively). All groups' healing rates improved at 12- and 24-month follow-ups, without significant between-group differences. Secondary end points of pain and disability were also similar. Lack of blinding might have led to differing levels of participation in other aspects of the treatment protocol.

A 2016 study by Zhai et al evaluated the use of human autologous bone mesenchymal stem cells (hBMSC) combined with ESWT for the treatment of nonunion long bones. Nonunion was defined as 6 or more months post fracture with no evidence of additional healing in the past 3 months. Patients were randomized to high-energy ESWT (n=31) or hBMCS plus ESWT (n=32). ESWT was administered every 3 days, 4 times for upper-limb nonunion and 5 times for lower-limb nonunion. Outcome measures were no pain, no abnormal mobility, x-ray showing blurred fracture line, and upper-limb holding 1 kg for 1 minute or lower-limb walking for 3 minutes. Success was defined as meeting all 4 criteria at 12 months. The hBMCS plus ESWT group experienced an 84% healing rate. The ESWT alone group experienced a 68% healing rate ($p<0.05$).

Section Summary: ESWT for Nonunion or Delayed Union of Acute Fracture
The evidence on the use of ESWT for the treatment of fractures or for fracture nonunion or delayed union includes several relatively small RCTs with methodologic limitations (e.g., heterogeneous outcomes and

treatment protocols), along with case series. The available evidence does not permit conclusions on the efficacy of ESWT in fracture nonunion, delayed union, or acute long bone fractures.

ESWT FOR SPASTICITY

Systematic Reviews

Lee et al (2014) conducted a meta-analysis of studies evaluating ESWT for patients with spasticity secondary to a brain injury. Studies included evaluated ESWT as sole therapy and reported pre- and postintervention Modified Ashworth Scale (MAS) scores. Five studies were selected, 4 examining spasticity in the ankle plantarflexor and one examining spasticity in the wrist and finger flexors; 3 studies evaluated poststroke spasticity and 2 evaluated spasticity associated with cerebral palsy. Immediately post-ESWT, MAS scores improved significantly compared with baseline (standardized mean difference [SMD], -0.792; 95% CI, -1.001 to -0.583; p<0.001). Four weeks post-ESWT, MAS scores continued to demonstrate significant improvements compared with baseline (SMD = -0.735; 95% CI, -0.951 to -0.519; p<0.001). A strength of this meta-analysis was its use of a consistent and well-definable outcome measure. However, the MAS does not account for certain clinically important factors related to spasticity, including pain and functional impairment.

Randomized Controlled Trials

The efficacy and safety of RSW in the treatment of spasticity in patients with cerebral palsy was examined in a small European RCT in 2011. The 15 patients in this trial were divided into 3 groups (ESWT in a spastic muscle, ESWT in both spastic and antagonistic muscle, placebo ESWT) and treated in 3 weekly sessions. Spasticity was evaluated in the lower limbs by passive range of motion with a goniometer and in the upper limbs with the Ashworth Scale (0 [not spasticity] to 4 [severe spasticity]) at 1, 2, and 3 months posttreatment. Blinded evaluation showed significant differences between the ESWT and placebo groups for range of motion and Ashworth Scale score. For the group in which only the spastic muscle was treated, there was a 1-point improvement on the Ashworth Scale (reported significant vs placebo); for the group with both spastic agonist and antagonist muscles treated, there was a 0.5-point improvement (p=*NS* vs placebo); and for the placebo group, there was no change. The significant improvements were maintained at 2 months posttreatment, but not at 3 months.

Noncomparative Studies

Daliri et al (2015) evaluated the efficacy of a single session of ESWT for the treatment of poststroke wrist flexor spasticity in a single-blinded trial in which each patient received sham control and active stimulation. Fifteen patients at a mean 30 months poststroke were included, each of whom received 1 sham stimulation followed 1 week later by 1 active ESWT treatment. Investigators were not blinded. Outcomes evaluated included MAS score to evaluate spasticity intensity, the Brunnstrom Recovery Stage tool to assess motor recovery, and the neurophysiological measure of Hmax/Mmax to measure alpha motoneuron excitability. MAS scores and Brunnstrom Recovery Stage scores did not improve after sham treatment. MAS scores improved significantly from baseline (mean, 3) to post active treatment (mean scores, 2, 2, and 2 immediately posttherapy, 1 week posttherapy, and 5 weeks posttherapy, respectively; p<0.05). The H-max/Mmax ratio improved from 2.30 before therapy to 1 the week after active ESWT (p=0.047). Brunnstrom

scores did not significantly improve after active ESWT. Given the lack of a control group, this study provides limited evidence on the comparative efficacy of ESWT for poststroke spasticity.

Santamato et al (2014) evaluated outcomes after a single session of ESWT for poststroke plantarflexor spasticity (equinus foot) in 23 subjects. Subjects with gastrocnemius/soleus Heckmann scores on ultrasound from I to III (maximum score, IV [very high muscle echo intensity due to fat and fibrosis]) had significant improvements in MAS scores from baseline to immediately post-ESWT (3.5 to 2.1, $p<0.01$) and from baseline to 30 days post-ESWT (3.5 to 2.6, $p<0.05$). Those with a Heckmann score of IV showed improvements in MAS scores from baseline to immediately post-ESWT (4.7 to 3.3, $p<0.05$), but 30-day scores did not differ significantly from baseline. Results were similar for passive ankle dorsiflexion scores.

Section Summary: ESWT for Spasticity
A relatively small body of evidence, with limited RCT evidence, is available on the use of ESWT for spasticity. Several studies have demonstrated improvements in spasticity measures after ESWT. More controlled trials are needed to determine whether ESWT leads to clinically meaningful improvements in pain and/or functional outcomes for spasticity.

ESWT FOR OTHER CONDITIONS
ESWT has been investigated in small studies for other conditions, including coccydynia in a case series of 2 patients and painful neuromas at amputation sites in a small RCT including 30 subjects.

In the systematic review of ESWT for lower-extremity tendinopathies (previously described) by Mani-Babu et al (2015) reviewed 2 studies of ESWT for greater trochanteric pain syndrome, including 1 quasi-RCT comparing ESWT with home therapy or corticosteroid injection and 1 case-control study comparing ESWT with placebo. ESWT was associated with some benefits compared with placebo or home therapy.

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 the same trials are included in both meta-analyses, pooled results were inconsistent. One meta-analysis reported that ESWT was beneficial in improving pain reduction, 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, the 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 recent 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 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, then H-FSW. Many of the RCTs are considered 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 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 reported that ESWT reduced both short- and long-term pain compared with nonoperative treatments, although the authors warned that results were inconsistent across the RCTs and that there was heterogeneity across studies in 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. 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, plus an RCT published after the systematic review. 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 MTSS 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 impacts the strength of the conclusions. The available evidence is limited and inconsistent; it does not permit conclusions about the benefits of ESWT for MTSS. 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 pain, particularly in patients with

early-stage osteonecrosis, the studies were low quality based on lack of blinding, lack of comparators, small ample sizes, and short follow-up. Treatment protocols also differed between studies. 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 a 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. The review 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 MAS 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.

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Policy History

Original Effective Date: 08/27/2001
Current Effective Date: 03/21/2018

08/16/2001	Medical Policy Committee review
08/27/2001	Managed Care Advisory Council approval
03/21/2002	Medical Policy Committee review. Coverage eligibility changed to reflect current literature.
03/25/2002	Managed Care Advisory Council approval
02/03/2004	Medical Director Review
02/17/2004	Medical Policy Committee review. Format revision. Coverage eligibility change to reflect the investigational status of the technology identified in current literature.
02/23/2004	Managed Care Advisory Council approval. Claims Processing effective date based on revised policy will be 4/1/04.
02/01/2006	Medical Director review
02/15/2006	Medical Policy Committee approval. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
02/23/2006	Quality Care Advisory Council approval
02/13/2008	Medical Director review
02/20/2008	Medical Policy Committee approval. No change to coverage eligibility.
02/04/2009	Medical Director review
02/19/2009	Medical Policy Committee approval. No change to coverage eligibility.
02/04/2010	Medical Director review
02/17/2010	Medical Policy Committee approval. Title changed to Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions.
02/03/2011	Medical Policy Committee review
02/16/2011	Medical Policy Implementation Committee approval. No change to coverage statement.
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. No change to coverage statement.
01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/04/2013	Coding revised
01/09/2014	Medical Policy Committee review
01/15/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/05/2015	Medical Policy Committee review
03/20/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
03/04/2016	Medical Policy Committee review

Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

Policy # 00039
Original Effective Date: 08/27/2001
Current Effective Date: 03/21/2018

03/16/2016	Medical Policy Implementation Committee approval. Added additional indications into coverage statement. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update
03/02/2017	Medical Policy Committee review
03/15/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/01/2018	Medical Policy Committee review
03/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2019

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code			
CPT	0101T, 0102T, 20999, 28890			
HCPCS	No codes			
ICD-10 Diagnosis	M48.40XA-M48.48XA	M62.40	M62.411-M62.479	M62.48-M62.49
	M62.831	M62.838	M72.2	M76.50-M76.52
	M76.60-M76.62	M77.10-M77.12	M80.00XK	M80.011K-M80.019K
	M80.021K-M80.029K	M80.031K-M80.039K	M80.041K-M80.049K	M80.051K-M80.059K
	M80.061K-M80.069K	M80.071K-M80.079K	M80.08XK	M80.80XK
	M80.811K-M80.819K	M80.821K-M80.829K	M80.831K-M80.839K	M80.841K-M80.849K
	M80.851K-M80.859K	M80.861K-M80.869K	M80.871K-M80.879K	M80.88XK
	M84.30XA, M84.30XK	M84.311A, M84.311K	M84.312A, M84.312K	M84.319A, M84.319K
	M84.321A, M84.321K	M84.322A, M84.322K	M84.329A, M84.329K	M84.331A, M84.331K
	M84.332A, M84.332K	M84.333A, M84.333K	M84.334A, M84.334K	M84.339A, M84.339K

	M84.341A, M84.341K	M84.342A, M84.342K	M84.343A, M84.343K	M84.344A, M84.344K
	M84.345A, M84.45K	M84.346A, M84.346K	M84.350A, M84.350K	M84.351A, M84.351K
	M84.352A, M84.352k	M84.353A, M84.353K	M84.359A, M84.359K	M84.361A, M84.361K
	M84.362A, M84.362K	M84.363A, M84.363K	M84.364A, M84.364K	M84.369A, M84.369K
	M84.371A, M84.371K	M84.372A, M84.372K	M84.373A, M84.373K	M84.374A, M84.374K
	M84.375A, M84.375K	M84.376A, M84.376K	M84.377A, M84.377K	M84.378A, M84.378K
	M84.379A, M84.379K	M84.38XA, M84.38XK	M84.40XK-M84.48XK	M84.50XK-M84.58XK
	M84.60XK-M84.68XK	M84.80	M84.811-M84.879	M84.8
	M84.9	M85.10	M85.111-M85.179	M85.18-M85.19
	M85.80	M85.811-M85.879	M85.88-M85.89	M87.051-M87.859
	M89.20	M89.211-M89.279	M89.28-M89.30	M89.311-M89.379
	M89.38-M89.39	M89.50	M89.511-M89.579	M89.58-M89.59
	M89.8X0-M89.8X9	M90.551-M90.559	M94.1	M94.351-M94.359
	M94.8X0-M94.8X9	S02.0XXK	S02.210XK	S02.110K-S02.119K
	S02.19XK	S02.2XXK-S02.3XXK	S02.400K-S02.402K	S02.411K-S02.413K
	S02.42XK	S02.5XXK	S02.600K	S02.609K
	S02.61XK-S02.69XK	S02.8XXK	S02.91XK-S02.92XK	S12.00K
	S12.001K	S12.01XK-S12.02XK	S12.030K-S12.031K	S12.040K-S12.041K
	S12.090K-S12.091K	S12.100K-S12.101K	S12.110K-S12.112K	S12.110K-S12.191K
	S12.200K-S12.2291K	S12.34XK	S12.350K-S12.351K	S12.390K-S12.391K
	S12.400K-S12.401K	S12.430K-S12.431K	S12.44XK	S12.450K-S12.451K
	S12.490K-S12.491K	S12.500k-S12.501K	S12.530K-S12.531K	S12.54XK
	S12.550K-S12.551K	S12.590K-S12.591K	S12.600K-S12.691K	S22.000K-S22.9XXK
	S32.000K-S32.9XXK	S42.001K-S42.92XK	S49.001K-S49.199K	S52.001K-S52.92XN
	S59.001K-S59.299K	S62.001K-S62.92XK	S72.001K-S72.92XN	S79.001K-S79.199K
	S82.001K-S82.92XN	S89.032K-S89.399K	S92.001K-S92.919K	

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

Policy # 00039
Original Effective Date: 08/27/2001
Current Effective Date: 03/21/2018

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.