

# EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT)

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[Instructions for Use](#) ⓘ

Table of Contents	Page
<a href="#">NON-COVERAGE RATIONALE</a> .....	1
<a href="#">APPLICABLE CODES</a> .....	1
<a href="#">DESCRIPTION OF SERVICES</a> .....	2
<a href="#">CLINICAL EVIDENCE</a> .....	2
<a href="#">U.S. FOOD AND DRUG ADMINISTRATION</a> .....	10
<a href="#">REFERENCES</a> .....	10
<a href="#">POLICY HISTORY/REVISION INFORMATION</a> .....	14
<a href="#">INSTRUCTIONS FOR USE</a> .....	14

## Related Policy

- [Lithotripsy for Salivary Stones](#)

## NON-COVERAGE RATIONALE

**Extracorporeal shock wave therapy (ESWT), whether low energy, high energy or radial wave, is unproven and not medically necessary for all indications, including but not limited to the treatment of:**

- Achilles tendonitis
- Calcaneal spur
- Calcific tendonitis of the shoulder (rotator cuff)
- Chronic plantar fasciitis (including plantar fibromatosis and plantar nerve lesion)
- Delayed or nonunion of fractures
- Hammer toe
- Lateral epicondylitis (tennis elbow)
- Medial epicondylitis (golfers elbow)
- Tenosynovitis of the foot or ankle
- Tibialis tendinitis
- Wounds including ulcers

The available evidence regarding the efficacy of ESWT is conflicting. There is insufficient evidence regarding the durability of the treatment effects of ESWT. Patient selection criteria have not been adequately defined and optimal treatment parameters have not been established. Finally, in some studies, ESWT is no more effective than sham treatment in relieving pain.

**Note:** This policy does not address extracorporeal shock wave lithotripsy (ESWL).

## APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

CPT Code	Description
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified high energy
0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle
0512T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound

CPT Code	Description
0513T	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each additional wound (List separately in addition to code for primary procedure)
28890	Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia

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## DESCRIPTION OF SERVICES

Extracorporeal shock wave therapy (ESWT) is a noninvasive treatment that involves delivery of shock waves to the painful region with the objective of reducing pain and promoting healing of the affected soft tissue. The shock waves for orthopedic indications are the same as those used to break up kidney stones, but have 10 times less energy. Low energy defocused ESWT or soft focused acoustical wave pattern is used for wound healing.

ESWT is evolving as a proposed treatment option for a variety conditions, including musculoskeletal disorders and wounds/soft tissue injuries. The mechanism by which ESWT might relieve pain associated with musculoskeletal conditions is unknown. It is thought to disrupt fibrous tissue with subsequent promotion of revascularization and healing of tissue. It has also been hypothesized that the shock waves may reduce the transmission of pain signals from the sensory nerves and/or stimulates healing. (Huang, et al., 2000)

Indications for ESWT, called orthotripsy when used in an orthopedic setting, include localized, painful musculoskeletal conditions such as plantar fasciitis associated with calcaneus bone spurs. In this situation, ESWT serves as an alternative to surgery for patients with chronic heel pain that has not responded to conservative therapy. Other chronic conditions for which ESWT has been proposed include epicondylitis humeri (tennis and golfer elbow), calcifying tendonitis in the shoulder (specifically rotator cuff), and promotion of bone healing in delayed and nonunion fractures and treatment of wounds. ESWT also has been used in experimentally to mobilize the cement used for total hip arthroplasty, since removal of the cement is a major impediment to replacement of a failed prosthesis. Techniques for using extracorporeal shock wave therapy for musculoskeletal problems have not yet been standardized and the precise dosages and the optimal frequency of application have not been studied extensively. (BlueCross BlueShield Technology Evaluation Center, 2005)

## CLINICAL EVIDENCE

### **Achilles Tendonitis**

ESWT has been investigated for a variety of tendinitis/tendinopathy syndromes including Achilles tendonitis. Conclusive evidence recommending ESWT as a treatment for Achilles tendinopathy is lacking. Studies comparing high energy, single-treatment protocols with low energy, multiple-treatment protocols, and studies comparing various dosing intervals and energy flux densities are also needed to determine optimal treatment parameters. A standardized method to evaluate results may also be helpful. Published articles on ESWT for Achilles tendonitis have been limited to studies using animal models. There are no adequate prospective clinical studies demonstrating the effectiveness of ESWT for Achilles tendonitis.

In 2015, Mani-Babu et al. reported results of a systematic review and meta-analysis of studies evaluating ESWT for lower limb tendinopathies, including Achilles tendinopathy. The review included 11 studies which evaluated ESWT for Achilles tendinopathy. In pooled analysis, the authors reported that ESWT was associated with greater short term (<12 months) and long-term (>12 months) improvements in pain and function compared with nonoperative treatments. The authors noted that findings from RCT's of ESWT for Achilles tendinopathy are contradictory, but that there is at least some evidence for short-term improvements in function with ESWT.

Rasmussen et al. (2008) conducted a randomized, double-blind, placebo-controlled trial to evaluate ESWT for Achilles tendinopathy. Forty-eight patients were equally divided to receive either ESWT or a sham treatment. The American Orthopaedic Foot and Ankle Society (AOFAS) score and pain was assessed before, during and at 4, 8, and 12 weeks after treatment. Two patients in the ESWT group and 1 in the placebo group were lost to follow-up. Of the remaining participants, both groups showed improvement during the treatment and follow-up period. The mean AOFAS score increased from 74 to 81 in the placebo group and from 70 to 88 in the ESWT group. Better results, however, were seen in the ESWT group at 8 and 12 weeks of follow-up. Pain was reduced in both groups but the difference between them was not statistically significant. The authors concluded that the evidence is currently not convincing to recommend ESWT for Achilles tendinopathy. Further studies are needed to explore the effects of other technologies. These should address higher energy per area, greater treatment area, and, if possible, one session of treatment.

## **Professional Societies**

### **National Institute for Health and Care Excellence (NICE)**

An updated 2016 guidance statement found that the current evidence on the efficacy of ESWT is inconsistent and poor quality NICE encourages further research into ESWT for Achilles tendinopathy, which may include comparative data collection. Studies should clearly describe patient selection, treatment protocols, use of local anaesthesia and the type and duration of energy applied. Studies should include validated outcome measures and have a minimum of 1 year of follow-up.

### **Calcaneal Spur**

A randomized controlled study by Tornese et al. (2008) compared extracorporeal shock wave therapy in 45 subjects with a history of at least 6 months of heel pain. Patients were randomized into 2 groups (perpendicular and tangential technique) with 2 and 8 months follow-up. Each subject received a three-session ultrasound-guided extracorporeal shock wave therapy (performed weekly). Mayo Clinical Scoring System was used to evaluate each subject before and after treatment. Mayo Clinical Scoring System pretreatment scores were homogeneous between the groups (group A 55.2 +/-18.7; group B 53.5 +/- 20; P>0.05). In both groups there was a significant (P<0.05) increase in the Mayo Clinical Scoring System score at 2 months (group A 83.9 +/- 13.7; group B 80 +/- 15,8) and 8 months (group A 90 +/- 10.5; group B 90.2 +/-8.7) follow-up. The authors concluded that there was no difference between the two techniques; however while the results appear promising additional studies with larger patient sample sizes are needed to further validate these results.

### **Calcific Tendinitis of the Shoulder (Rotator Cuff)**

In these studies, outcomes appeared to be related to level of energy applied to the injured region, with some pain relief provided by low-energy ESWT, and more sustained relief of pain and improvement of function after high-energy ESWT. Few of the studies provided data on the long-term effects of ESWT. However, there is some evidence to suggest that relief may be sustained in patients who have radiographic evidence of disintegration of calcium deposits after lithotripsy treatment.

The 12 studies of calcific tendonitis (n=948) included 4 randomized controlled trials (RCTs), 3 of which were placebo-controlled. Selection criteria were fairly uniform across studies. Most studies included only patients with symptoms for at least 12 months and who had failed conservative treatment in the previous 6 months, with some studies specifying a minimum number of failed treatments. Approximately half the studies required that patients observe a period without treatment prior to initiation of the study intervention and did not allow additional treatments during the follow-up period other than exercises or physical therapy; most studies did not report any assessment of compliance. The other studies did not provide information about whether patients were told not to use secondary treatments.

Follow-up in these studies ranged from 3 months to 4 years. All patients made improvements following ESWT, but improvements were not always statistically significant or significantly greater than those in the control/comparison group. Constant and Murley scale (CMS) scores (an outcome measure) at 6 months following last treatment ranged from 67.7 to 88.0, representing improvements of 25 to 35 points in four studies. Scores at 1 year were slightly better or slightly worse than 3- or 6-month scores (3 studies, n=274). Comparisons of different doses of ESWT suggested a dose-response relationship but do not identify a clear threshold.

In a 2013 systematic review and meta-analysis, Ioppolo et al. included six RCTs on ESWT compared to sham treatment or placebo for calcific shoulder tendinopathy. Greater shoulder function and pain improvements were found at 6 months with ESWT over placebo. However, most studies were considered to be low quality.

Lee et al. (2011) performed a systematic review of RCTs examining the midterm effectiveness of ESWT for calcified rotator cuff tendinitis. The review found consistent evidence of midterm effectiveness of ESWT in reducing pain and improving shoulder function. However it was determined that the different outcome measures used and inadequate reporting details in the included studies did not permit a quantitative synthesis of the effectiveness of this treatment. A lack of follow up period beyond one year in the studies was also a limitation and did not allow for conclusions to be made on the longer term effectiveness of ESWT.

In a single-blinded, randomized controlled trial, Engebretsen et al (2011) compared radial ESWT to supervised exercise in 104 patients with subacromial shoulder pain. At the conclusion of the study (1 year), no significant differences were seen between the two groups.

### **Chronic Plantar Fasciitis (Including Plantar Fibromatosis and Plantar Nerve Lesion)**

Plantar fasciitis may have several different clinical presentations but generally causes sharp pain in the heel that is more severe first thing in the morning or after an extended period of rest, and decreases gradually with walking. Current literature suggests that plantar fasciitis should be referred to as plantar fasciosis, as chronic disease may be due to degeneration rather than inflammation. Although pain may occur along the entire course of the plantar fascia,

it is usually limited to the inferior medial aspect of the calcaneus at the medial process of the calcaneal tubercle. There is generally no history of trauma. Plantar fasciitis is typically diagnosed by medical history, physical examination, and x rays, with other imaging tests such as magnetic resonance imaging or ultrasonography used only if necessary. (Menz, 2008; Tahririan et al., 2012; Landorf, 2015)

Sun et al. (2017) performed a meta-analysis of RCTs (n=9 studies/935 subjects) to compare the effectiveness of general ESWT, focused shock wave (FSW), and radial shock wave (RSW) to placebo for chronic plantar fasciitis. Limitations of the analysis include the lack of comparison to established treatment methods. The authors concluded that FSW may be associated with higher success rate and greater pain reduction compared to sham therapy in chronic plantar fasciitis patients. However, additional high-quality clinical trials and systemic reviews are needed to demonstrate the efficacy of ESWT (e.g., FSW, RSW therapies) and determine whether RSW therapy is an ideal alternative therapeutic method to conservative treatment and surgery

A 2016a Medical Technology Directory report for Focused Extracorporeal Shock Wave Therapy for Chronic Plantar Fasciitis reviewed 17 randomized controlled trials (RCTs). A large body of moderate-quality evidence suggests that although there is some evidence that ESWT may decrease patient-reported pain and increase functional outcomes in the short term for patients with plantar fasciitis, results are conflicting. Notably, unlike an older report on this topic, no pattern of differential effectiveness was observed between patients receiving high-energy versus low-energy ESWT. Limitations of the body of evidence include conflicting findings across studies as well as methodological weaknesses of individual studies, including lack of blinding, confounding due to secondary treatments, and high loss to follow-up. Focused ESWT appears to be relatively safe. Most complications reported in the reviewed studies were transient and consisted primarily of pain or discomfort during or just after treatment, swelling, and bruising. Additional controlled, blinded long-term safety and effectiveness data are needed.

Another 2016 published Hayes Directory Report reviewed available literature on radial ESWT for chronic plantar fasciitis. Outcomes measures in the studies were patient-rated pain on VAS, pain threshold, functional measures, QOL, overall treatment success, and complications. Although some of the moderate-size body of evidence suggested that radial ESWT may decrease patient-reported pain and increase functional outcomes in the short term, results were conflicting. The overall quality of the evidence was low with a small amount of long-term safety data available. Limitations of the evidence includes methodological weaknesses of individual studies such as lack of long-term follow-up, confounding due to secondary treatments, and high loss of follow-up. Similar to the findings of focused ESWT for the treatment of plantar fasciitis, it was concluded that additional controlled, blinded long-term studies are needed to assess the safety and effectiveness of radial ESWT.

Gollwitzer et al. (2015) published the results of a double-blind RCT involving 250 subjects with plantar fasciitis randomized to ESWT or placebo intervention and followed for 12 weeks post-treatment. The authors reported that the visual analog scale composite score showed a significant difference in the reduction of heel pain in the ESWT group vs. the placebo group (69.2% vs. 34.5 %). They also stated that the ESWT group demonstrated significantly superior results on the Roles and Maudsley score, a subjective 4-point patient assessment of pain and limitations of activity. No test for the accuracy of the blinding was conducted.

In 2014, Yin and colleagues published a systematic review and meta-analysis of studies involving ESWT for plantar fasciitis. The authors included a total of seven studies that were either RCTs or quasi-RCTs involving subjects with plantar fasciitis of at least 6 months duration. The primary outcome was treatment success rate. Among the five studies included in the pooled analysis for low energy devices, the result indicated that low energy ESWT was more likely to lead to treatment success than control treatment. However, the authors noted significant heterogeneity in the definitions for treatment success across studies. The pooled analysis for high energy ESWT devices involved two studies, and no difference between the ESWT and control treatments was reported. This study is hampered by the heterogeneity of the definition of treatment success across studies, as well as the basic issues of the base studies themselves, which are addressed above.

Dizon et al. (2013) conducted a systematic review and meta-analysis of clinical trials (2002-2010) to evaluate the effectiveness of ESWT in treating chronic plantar fasciitis. Eleven studies were included in this review. The primary outcome measure of interest was overall pain in the morning and during activity. Compared to placebo control, ESWT was more effective in reducing morning pain. There was no difference between ESWT and control in decreasing overall pain; however moderate-intensity ESWT was more effective in decreasing overall activity pain. There was no significant difference in the effectiveness of decreasing activity pain. Both moderate-and high-intensity ESWT were more effective in improving functional outcome. Acknowledged study limitations include the lack of consistency in outcome measure, specified dose intensities and follow-up.

The ECRI Institute issued an evidence report on the use of ESWT for the treatment of plantar fasciitis in 2013. The updated report included information from 37 clinical studies (Of these studies, 13 randomized controlled trials [RCTs] and 7 prospective case series were also included in the 2006 report). The data reported by these studies were

combined by meta-analysis. Study results indicated that patients treated with a single session of high energy ESWT had less pain on the first few steps in the morning than patients given a sham treatment. No evidence-based conclusion could be reached by ECRI as to whether patients treated with a course of low or medium energy ESWT had less, more, or the same amount of pain than patients given a sham treatment. It was summarized that ESWT is a safe procedure that may provide some relief from the pain of chronic plantar fasciitis; however, the degree of pain relief may not be clinically significant. An update to this evidence report states that Insufficient evidence was available to support any evidence-based conclusions about ESWT and about the safety and effectiveness of ESWT compared with other treatments for plantar fasciitis. (ECRI, 2013)

Overall, there is conflicting evidence regarding the benefits of ESWT for plantar fasciitis. Because of the variable natural history of plantar fasciitis and the subjective nature of the outcome measures, randomized controlled trials (RCTs) are needed to determine whether outcomes are improved with ESWT. Significant questions remain that warrant investigation in a large, well designed and conducted double-blind randomized trials. Therefore, no reliable conclusions can be reached concerning ESWT for the treatment of plantar fasciitis.

### **Low-Energy (LE) ESWT**

With respect to simple measures of pain, mean scores consistently showed short-term improvement following ESWT. Sham treatment produced short-term pain improvement but it was usually less, and the difference between sham and active ESWT was not always statistically significant. Between-group differences in the magnitude of pain improvement were found to be statistically significant by Cosentino et al. (2001) but were not significant in the studies by Buchbinder et al. (2002) and Speed et al. (2003). Buchbinder et al. also found improvement in both groups on several functional measures at 3 months, but between-group differences were insignificant.

Kudo et al. (2006) randomized 114 adults with chronic plantar fasciitis recalcitrant to conservative therapies for at least 6 months into two groups. One group received a single session of ESWT, the other group received placebo. The ESWT treated group demonstrated a statistically significant improvement in pain from baseline to 3 months according to Visual Analog Scale scores and in Roles and Maudsley Scores.

### **High-Energy (HE) ESWT**

Short-term follow-up revealed mean reduction in pain for both the intervention and placebo/comparison groups, with greater improvement in the patients who received active ESWT. Differences in both pain scores and in the proportion of patients who experienced clinical success were statistically significant. Long-term follow-up appears to suggest greater maintenance of success in patients who received ESWT than in patients allocated to placebo, but these results may be biased by the exclusion of losses to follow-up from analysis.

While studies of HE-ESWT appear to have more positive and more robust results, none of the reviewed studies directly tested the comparative efficacy of HE ESWT versus typical LE-ESWT, and a meta-analysis by Thomson et al. (2005) questions the clinical significance of the treatment effect. The meta-analysis evaluated the data from 897 patients and resulted in a pooled estimate of a mean 0.42-point reduction (confidence interval 0.02-0.82) on a 0 to 10 VAS in morning pain at 3 months. This mean difference was statistically significant. However, the authors question its clinical relevance because after the removal of the biggest source of bias (the two poorest quality studies), the results were not significant. Furthermore, the authors tested for heterogeneity of effect in terms of VAS pain scores among six studies. They found no evidence of heterogeneity, which suggests that the effectiveness of ESWT does not depend on energy level.

Malay et al. (2006) conducted a randomized, controlled, double-blinded, multicenter comparison of ESWT vs. placebo for plantar fasciitis. Patients were treated once by ESWT at energy levels (0.22 mJ/mm<sup>2</sup> to 0.32 mJ/mm<sup>2</sup>) (n = 115) or placebo control (n = 57). The VAS was used to measure results at three months follow-up. According to the blinded assessor, heel pain displayed a mean reduction of 2.51 in the ESWT group and 1.57 in the placebo group; this was statistically significant. According to the patients' self-assessment, heel pain displayed a mean reduction of 3.39 in the ESWT group and 1.78 in the placebo group, also statistically significant.

Wang et al. (2006) compared results of high-energy ESWT (n = 79 patients, 85 heels) vs. conservative treatment (n = 70 patients, 83 heels) for plantar fasciitis. Patients in the shockwave group received 1500 impulses at 16 kV (0.32 mJ/mm<sup>2</sup>) in a single session. Patients in the control group received conservative treatment consisting of nonsteroidal anti-inflammatory drugs, orthotics, physical therapy, an exercise program, and/or a local cortisone injection. Patients were evaluated with a 100 point scoring system with 70 points for pain and 30 points for function. Before treatment, the groups had no significant differences in the scores for pain and function. The shockwave group was evaluated at 60 to 72 months; the conservative treatment group was evaluated at 34 to 64 months. Overall results for the shockwave group were 69.1% excellent, 13.6% good, 6.2% fair, and 11.1% poor. Overall results for the control group were 0% excellent, 55% good, 36% fair, and 9% poor. The shockwave group had a recurrence rate of 11%; the control group had a recurrence rate of 55%. There were no systemic or local complications. The study weaknesses include evaluations were performed at different follow-up times and 70% of the score was subjective.

In the following, the clinical evidence from individual studies is summarized in greater detail. The two studies by Ogden et al. (2001, 2004a) are based on the same protocol and appear to represent an overlap in patients. Forty-seven percent of intervention patients and 30% of placebo patients had successful outcomes at 3 months; this difference was statistically significant. Patients who failed placebo treatment and elected crossover treatment had a success rate of 43% after another 3 months. Success was maintained at 1 year for 93% of ESWT patients, 60% of placebo patients, and 83% of patients who crossed over from placebo; however, the statistical analysis for these data was unclear. Following the initial randomized treatment, only 22% of the ESWT group chose retreatment, whereas 43% of the placebo group chose crossover treatment. This suggests greater patient satisfaction with ESWT.

### **Radial ESWT**

Gerdesmeyer et al. (2008) conducted a multi-center, randomized controlled trial of 245 patients comparing radial extracorporeal shock wave therapy (which works on the superficial skin layers) and placebo in the treatment of chronic plantar fasciitis. All patients underwent 3 interventions. Primary endpoints were changes in visual analog scale composite score from baseline to 12 weeks' follow-up, overall success rates, and success rates of the single visual analog scale scores (heel pain at first steps in the morning, during daily activities, during standardized pressure force). Secondary endpoints were single changes in visual analog scale scores, success rates, Roles and Maudsley score, SF-36, and patients' and investigators' global judgment of effectiveness 12 weeks and 12 months after extracorporeal shock wave therapy. Radial extracorporeal shock wave therapy proved significantly superior to placebo with a reduction of the visual analog scale composite score of 72.1% compared with 44.7% ( $P = .0220$ ), and an overall success rate of 61.0% compared with 42.2% in the placebo group ( $P = .0020$ ) at 12 weeks. Superiority was even more pronounced at 12 months, and all secondary outcome measures supported radial extracorporeal shock wave therapy to be significantly superior to placebo ( $P < .025$ ). The authors concluded that radial extracorporeal shock wave therapy significantly improves pain (based on visual analog scale and self-report), function, and quality of life compared with placebo in patients with recalcitrant plantar fasciitis. While the results of this study are promising, the results are not statistically significant when compared to chance; therefore, additional studies with long term follow-up and objective evaluation are needed.

A prospective, randomized, double-blind study by Ibrahim et al. (2010) compared radial extracorporeal shock wave therapy (RSWT) to placebo in the treatment of chronic plantar fasciitis. Fifty patients with unilateral, chronic plantar fasciitis were evenly divided to receive either RSWT ( $n = 25$ ) or placebo treatment ( $n = 25$ ). Patients in the RSWT group had RSWT applied in two sessions 1 week apart. The placebo group had treatment performed with a clasp on the heel. Outcomes (pain and quality of life) were measured at 4, 12 and 24 weeks by visual analog scale (VAS) and the modified Roles & Maudsley score. In the RSWT group, 92% (23/25) reported a percentage decrease in the VAS score larger than 60% from baseline at 4 weeks after the first session. Only 4% of the placebo group had a percentage decrease in the VAS score. At 24 weeks after the first session, the corresponding numbers were 100% (25/25) for the RSWT patients and 16% (4/25) for the placebo group. The authors concluded that radial extracorporeal shock wave therapy can reduce pain and increase quality of life with only 2 treatments. While results are promising, the study is limited by small sample size and short term follow-up.

A detailed search of the medical peer-reviewed literature did not identify any clinical studies that evaluated extracorporeal shock wave therapy for the treatment of plantar fibromatosis or plantar nerve lesion.

### **Professional Societies/Technology Assessments**

#### **National Institute for Health and Care Excellence (NICE)**

A 2009 guidance statement found that the current evidence on the efficacy of ESWT is inconsistent and should only be used with special arrangements for clinical governance, consent and audit or research. NICE encourages further research into ESWT for refractory plantar fasciitis in the form of clinical studies with clearly described patient selection and treatment protocols, including a description of local anesthesia use and the type of energy applied.

#### **American College of Foot and Ankle Surgeons (ACFAS)**

In a 2010 clinical practice guideline, ACFAS recommends that for those patients who fail to have improvement in pain after 6 months of conservative therapy, treatment options may include surgical plantar fasciotomy and extracorporeal shock wave therapy. (Thomas et al., 2010)

#### **American College of Occupational and Environmental Medicine (ACOEM)**

In a 2011 clinical practice guideline, ACOEM stated that there is insufficient evidence concerning ESWT for treating heel pain from plantar fasciitis.

A 2016 report issued by the Canadian Agency for Drugs and Technologies in Health (CADTH) reviewed evidence ( $n=7$  systematic reviews) on the effectiveness of shockwave therapy for pain associated with lower extremity orthopedic

disorders including plantar fasciitis. It was concluded that more evidence is needed to determine whether SWT is more clinically effective than surgery for pain associated with lower extremity orthopedic disorders (CADTH, 2016).

A technology assessment of RCTs evaluating the safety and efficacy of ESWT for the treatment of chronic plantar fasciitis was performed for **the Canadian Agency for Drugs and Technologies in Health (CADTH)**. Ho (2007) concluded "the lack of convergent findings from these randomized trials of ESWT for plantar fasciitis suggests uncertainty about its effectiveness. The evidence reviewed does not support the use of this technology for this condition" (Ho, 2007).

### **Delayed or Nonunion Fractures**

The data regarding the effect of ESWT for treatment of delayed or nonunion fractures is less convincing, due primarily to the fact that none of the studies controlled for potential effects of time and immobilization, Valchanou and Michailov (1991), Schleberger and Senge (1992), Birnbaum (2002). This is an important consideration, since delayed unions may eventually resolve spontaneously or with adequate immobilization alone. Moreover, the criteria used to define delayed union, pseudoarthrosis, or nonunion in these studies were not well defined, nor was it clearly stated how fracture healing was determined. None of the studies on fracture healing compared ESWT with other nonsurgical treatments for delayed fracture healing and fracture nonunion, such as electromagnetic and ultrasound bone stimulators.

Elster, et al. (2010) conducted a study with one hundred ninety-two patients were treated with ESWT at a single referral trauma center for treatment for tibia nonunion. Nonunion was determined by radiographic or CT analysis at least six months following operative or nonoperative treatment, with at least three months of no radiographic changes. Fracture healing was determined by radiographic or CT analysis. At the time of last follow up, 138 of 172 (80.2%) patients demonstrated complete fracture healing. Mean time from first shock wave therapy to complete healing of the tibia nonunion was 4.8 months. Associated factors influencing fracture healing included number of orthopedic operations shock wave treatments and pulses delivered. Patients requiring multiple (more than one) shock wave treatments versus a single treatment had a significantly lower likelihood of fracture healing. This study concludes that high energy ESWT may be used successfully in the treatment of tibia nonunions. The reported healing rate of 80%. The large sample size gives this study relevance; however, limitations include retrospective design and lack of a control group using immobilization alone. Although this study evaluated nonunion of tibia fractures, there is potential for future investigation of ESWT in the treatment of fracture and arthrodesis nonunion in the foot and ankle.

Zelle et al. (2010) conducted a systematic review to evaluate the results of ESWT in the treatment of fractures and delayed unions/nonunions. Ten studies were included and involved 924 patients who underwent 1 to 3 treatment sessions. The overall union rate in patients with delayed union/nonunion was 76% and ranged from 41% to 85%. The authors concluded that while promising, ESWT for the treatment of fractures and delayed unions/nonunions requires further studies. Additional studies need to investigate how shock wave therapy compares with other treatment approaches and if different anatomic fracture locations demonstrate different success rates. In addition, the optimal treatment dose needs to be identified in further investigations.

A randomized controlled trial by Cacchio et al. (2009) compared extracorporeal shock wave therapy with surgical treatment in 126 patients with long-bone non-unions. Outcomes were measured using x-rays. Each group showed the same amount of healing at 6, 12 and 24 months. The authors concluded that extracorporeal shock-wave therapy is as effective as surgery in stimulating union of long-bone hypertrophic non-unions. The study is limited by lack of blinding and a control group. Additional studies are needed to further validate the results.

Further research in this area in the form of a large-scale randomized trial is necessary to better answer the question of the effectiveness of extracorporeal shockwave therapy in union rates for both nonunions and acute fractures.

### **Hammer Toe**

A detailed search of the medical peer-reviewed literature did not identify any clinical studies that evaluated extracorporeal shock wave therapy for the treatment of hammer toe.

### **Lateral Epicondylitis (Tennis Elbow)**

Lateral epicondylitis is the most common form of tendinitis of the elbow, and results in lateral elbow pain and functional limitations. The disorder is caused by overuse or injury of the tendons that attach the arm muscles to the elbow, such as commonly occurs from playing tennis ("tennis elbow"). Lateral epicondylitis is caused by repetitive motion that exerts stress on the grasping muscles of the forearm, which originate at the lateral epicondyle of the elbow. Conservative treatment involves rest, ice, stretching, strengthening, activity modification, and, as healing occurs, strengthening exercises. (Bhabra et al. 2016)

The mechanism of action of extracorporeal shock wave therapy in the treatment of lateral elbow pain is not well understood. Techniques for using extracorporeal shock wave therapy for musculoskeletal problems have not yet been

standardized and the precise dosages and the optimal frequency of application have not been studied extensively. There is still no consensus on when to differentiate between low and high-energy shock wave applications. The studies selected for this update include randomized controlled trials (RCTs) and randomized comparative trials of ESWT for the treatment of chronic lateral epicondylitis. Because the ESWT administered in most of these studies fell within a fairly narrow range, no analysis of low energy versus high energy was attempted. (Buchbinder et al. 2002)

Capan et al. (2016) conducted a double-blind, randomized, placebo-controlled trial was conducted in outpatient clinics in a medical faculty hospital. Fifty-six patients with lateral epicondylitis were randomized to rESWT or sham rESWT groups. Both the patients and the outcome assessing investigator were blinded to group assignment. The rESWT was administered to the painful epicondyle at the elbow at each session at three once weekly sessions. Sham rESWT was applied without the contact of the applicator at the same area. Study patients were assessed at baseline and at 1 and 3 mos after treatment using a visual analog scale for pain and Roles and Maudsley scale and Patient-Rated Tennis Elbow Evaluation for pain and function. Grip strength of the affected extremity was also measured using a hand dynamometer. Both rESWT and sham rESWT groups showed a significant improvement in all outcome measures at post treatment follow-up points. Favorable absolute and percentage changes in assessments at 1- and 3-mo post treatment did not show any significant difference between groups. The authors concluded rESWT does not seem to be more effective either in reducing pain or improving function or grip strength in patients with lateral epicondylitis at least at 3 mos after treatment when compared with sham rESWT.

Staples et al. (2008) conducted a double-blind, randomized controlled trial on 68 patients to determine whether ultrasound-guided extracorporeal shock wave therapy (ESWT) reduced pain and improved function in patients with lateral epicondylitis (tennis elbow) in the short term and intermediate term. Patients were randomized to receive 3 ESWT treatments or 3 treatments at a subtherapeutic dose given at weekly intervals. Seven outcome measures relating to pain and function were collected at follow-up evaluations at 6 weeks, 3 months, and 6 months after completion of the treatment with mean changes compared for the 2 groups. The groups did not differ on demographic or clinical characteristics at baseline and there were significant improvements in almost all outcome measures for both groups over the 6-month follow-up period, but there were no differences between the groups even after adjusting for duration of symptoms. The authors concluded that there was little evidence to support the use of ESWT at a therapeutic or subtherapeutic dose for the treatment of lateral epicondylitis.

Pettrone and McCall (2005) found that patients who crossed over after unsuccessful sham treatment had significantly better 3-month results following active treatment. For simple measures of pain, studies generally showed short-term improvement following active, full-dose ESWT. Percent improvement in pain score at 3 months ranged from 33% to 70% and at 6 months from 55% to 79%. However, four studies (total n=493) failed to demonstrate a significant treatment effect of ESWT, Chung and Wiley (2004), Haake et al. (2002a), Melikyan et al. (2003), Speed (2002). Although there was short-term improvement in pain following ESWT in these studies, there was also a reduction in pain with sham treatment, and the difference was not significant. Three study assessments at 1 year reported that pain scores for patients treated with ESWT had improved more than 50% from baseline, but 1-year group differences were not statistically significant in any of these studies. (Melikyan et al. (2003), Pettrone and McCall (2005), Rompe et al. (2004))

These studies did not provide definitive evidence that ESWT contributed to relevant overall clinical improvement in terms of subsequent treatment, global assessments, or functional outcomes. Melikyan et al. (2003) observed nonsignificant differences in the use of analgesics after treatment and in subsequent surgery. The two earliest studies by Rompe et al. (2004) observed statistically significant short-term differences between full-dose and minimal-dose groups in grip strength, but the other studies that assessed grip strength observed only small or statistically nonsignificant differences at both short-term and 1-year follow-ups. Although Pettrone and McCall (2005) found significant 3-month differences in Upper Extremity Functional Scale (UEFS) and activity scores, no significant group differences were found in Disabilities of the Arm, Shoulder, and Hand, UEFS, or quality of life scores in three other studies. Short-term rates of clinical success ranged from 26% to 65%; group differences were significant or untested in the studies reporting a positive treatment effect and not significant in the others. Success rates at 1 year ranged from 66% to 81%; all group differences were not significant, although in two studies, the ESWT group exhibited numerically much better results. (Pettrone and McCall (2005), Rompe et al. (2004))

### **Professional Societies/Technology Assessments**

#### **American College of Occupational and Environmental Medicine (ACOEM)**

In a 2012 clinical practice guideline, ACOEM stated that ESWT for elbow disorders was considered, but is not currently recommended.

#### **BlueCross BlueShield Association Technology Evaluation Center**

An assessment from the BlueCross BlueShield Association Technology Evaluation Center (2005) concluded that ESWT for lateral epicondylitis does not meet the TEC criteria. The assessment explained that "overall, the available data does not provide strong and consistent evidence that ESWT improves outcomes of chronic lateral epicondylitis."



## **California Technology Assessment Forum (CTAF)**

A 2004 Technology Assessment from California Technology Assessment Forum (CTAF) found "pain from LE tends to resolve over extended periods of time, even for patients who have failed conservative therapy for many months. Therefore, uncontrolled studies of ESWT, while promising, may represent the natural history of the disorder abetted by a strong placebo effect. Studies with pain as the primary outcome commonly are subject to large placebo effects. The CTAF also highlighted results from a systematic review from 2000 that identified 20 studies of ESWT for lateral epicondylitis (Boddeker et al.). According to CTAF, each study had methodological flaws and there was no difference in the degree of improvement in pain between groups in higher quality RCTs. Both ESWT groups and sham ESWT groups showed improvements in pain, function and grip strength over six weeks to one year of follow-up. Between group differences were negligible and sometimes favored the sham group.

Additional randomized controlled trials of ESWT for elbow tendinopathy have been published. However, these trials have significant methodological limitations such as small study populations and short duration of follow up. At this time, there is not enough evidence in medical literature to support the efficacy of ESWT for lateral epicondylitis.

## **National Institute for Health and Care Excellence (NICE)**

A 2009 guidance statement found that the current evidence on the efficacy of ESWT is inconsistent and should only be used with special arrangements for clinical governance, consent and audit or research. NICE encourages further research into ESWT for refractory tennis elbow in the form of clinical studies with clearly described patient selection and treatment protocols, including a description of local anesthesia use and the type of energy applied.

## **Tenosynovitis of the Foot or Ankle**

A detailed search of the medical peer-reviewed literature did not identify any clinical studies that evaluated extracorporeal shock wave therapy for the treatment of tenosynovitis of the foot or ankle.

## **Tibialis Tendonitis**

A detailed search of the medical peer-reviewed literature did not identify any clinical studies that evaluated extracorporeal shock wave therapy for the treatment of tibialis tendonitis.

## **Wounds**

ESWT has been proposed as a treatment for delayed/nonhealing or chronic wounds. The mechanism by which ESWT may provide a therapeutic effect in wounds remains unclear. Potential mechanisms include durable and functional neovascularization and the reduction of proinflammatory effects that inhibit wound healing.

Omar et al. (2017) performed a systematic review of 10 databases for clinical trials about ESWT in the management of CWLE. These were published between 2000 and 2016. A total of 11 studies with 925 patients were found. Expert therapists assessed the methodological qualities of the selected studies using the Physiotherapy Evidence Database (PEDro) scale and categorized each study according to Sackett's levels of evidence. Eight studies were categorized as level II; two studies were categorized as level III and one study was categorized as level V. In conclusion, this review demonstrated mild to moderate evidence to support the use of ESWT as an adjuvant therapy with a standardized wound care programme. However, it is difficult to draw firm conclusions about the efficacy of ESWT. So, future researches with high methodological quality are required to assess the efficacy and cost-effectiveness of this relatively new physical therapy application.

In a phase II randomized controlled trial, Ottomann et al. (2011) evaluated shock wave effects in burn wounds. A predefined cohort of 50 patients (6 with incomplete data or lost to follow-up) with acute second-degree burns were randomly to receive standard therapy (burn wound debridement/topical antiseptic therapy) with (n = 22) or without (n = 22) defocused ESWT applied once to the study burn, after debridement. Randomization sequence was computer-generated, and patients were blinded to treatment allocation. Mean time to complete ( $\geq 95\%$ ) epithelialization (CE) for patients that did and did not undergo ESWT was  $9.6 \pm 1.7$  and  $12.5 \pm 2.2$  days, respectively. The authors concluded that the application of a single defocused shock wave treatment to the superficial second-degree burn wound after debridement/topical antiseptic therapy significantly accelerated epithelialization. However, they also indicated that this finding warrants confirmation in a larger phase III trial.

Ottomann et al. (2010) evaluated the use of extracorporeal shock wave therapy for the revascularization and repair of healing soft tissue. Twenty-eight patients with acute traumatic wounds and burns requiring skin grafting were randomly assigned in a 1:1 fashion to receive standard topical therapy (nonadherent silicone mesh and antiseptic gel) to graft donor sites with (n = 13) or without (n = 15) defocused ESWT applied once to the donor site, immediately after skin harvest. The randomization sequence was computer generated, and the patients were blinded to treatment allocation. Mean times to complete graft donor site epithelialization for patients who did and did not undergo ESWT were  $13.9 \pm 2.0$  days and  $16.7 \pm 2.0$  days, respectively. The authors concluded that for centers that apply

nonadherent gauze dressings and topical antiseptics to skin graft donor sites, application of a single defocused shock wave treatment immediately after skin graft harvest can significantly accelerate donor site epithelialization. This study is limited by a small study population.

Larking et al. (2010) assessed whether extracorporeal shock wave therapy increases the rate of healing in chronic decubitus ulceration in a double-blind randomized cross-over study. Ulcers were randomized into receiving either the extracorporeal shock wave therapy or the placebo for a four-week period, followed by a two-week 'washout' period followed by a four-week period of the cross-over treatment/ placebo. Nine ulcers (in eight patients) were included in the study. All those with static chronic ulcers showed improved healing starting 6-8 weeks after the start of extracorporeal shock wave therapy, whether treated first with the placebo or the therapy. The authors concluded that extracorporeal shock wave therapy has a potential part to play in the treatment of chronic skin ulceration. This study is limited by a small study population.

Wang et al. (2011) investigated the molecular changes of extracorporeal shockwave therapy (ESWT) and hyperbaric oxygen therapy (HBOT) in chronic diabetic foot ulcers. The cohort study consisted of 39 patients (44 ulcers) in the ESWT group and 38 patients (40 ulcers) in the HBOT group with similar demographic characteristics. The ESWT group received shockwave therapy twice per week for total six treatments. The HBOT group received hyperbaric oxygen therapy daily for total 20 treatments. Biopsy was performed from the periphery of the ulcer before and after treatment. Significant increases in immuno-activity expression were noted after ESWT, whereas the changes after HBOT were statistically not significant. The differences of immuno-activity expressions between the two groups were comparable before treatment; however, the differences became statistically significant after treatment favoring the ESWT group. The authors concluded that ESWT showed significant increases in angiogenesis and tissue regeneration over HBOT in diabetic foot ulcers. This study is limited by a small study population. No outcomes regarding ulcer healing were reported.

Moretti et al. (2009) evaluated if ESWT is effective in the management of neuropathic diabetic foot ulcers in a randomized, prospective, controlled study. The study included 30 patients affected by neuropathic diabetic foot ulcers who were divided into two groups based on different management strategies. One group was treated with standard care and shock wave therapy. The other group was treated with only standard care. The healing of the ulcers was evaluated over 20 weeks by the rate of re-epithelization. After 20 weeks of treatment, 53.33% of the ESWT-treated patients had complete wound closure compared with 33.33% of the control patients, and the healing times were 60.8 and 82.2 days, respectively. The authors concluded that ESWT may be a useful adjunct in the management of diabetic foot ulceration. Additional studies with larger patient populations are needed to validate the conclusions of this study.

Wolff et al. (2011) assessed the possible effects of comorbidities and of different wound etiologies on the success of ESWT of chronic soft tissue wounds in 258 patients. The patients underwent follow-up for a median of 31.8 months. Wound closure occurred in 191 patients (74.03%) by a median of two treatment sessions. No wound reappeared at the same location. A multivariate logistic regression model showed that pooled comorbidities and wound etiologies did not have a significant influence on success. The lack of a control group limits the validity of the conclusions of this study.

In a systematic review which included three randomized controlled trials, one quasi-experimental study, and one case series, Butterworth et al. (2015) found that although these studies showed improvement in wound healing following ESWT, evidence was limited. The authors concluded that further research is needed on the use of extracorporeal shock wave therapy for the treatment of lower limb ulceration due to the limited evidence available.

Although initial results from several RCTs and case series suggest that ESWT may promote wound healing, well-designed RCTs with larger patient populations and long-term follow-up are needed to support this wound treatment modality.

## U.S. FOOD AND DRUG ADMINISTRATION (FDA)

The FDA has classified extracorporeal shock wave therapy (ESWT) products as class III devices through the premarket approval program (PMA) under the product code NBN (generator, shock-wave, for pain relief).

Devices used for extracorporeal shock wave therapy are extensive. See the following website for more information and search by product name in device name section: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>. (Accessed March 20, 2018)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2018T0269V]

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## POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2019	<ul style="list-style-type: none"><li>• Simplified policy template; removed <i>Applicable Lines of Business/Products</i> section</li><li>• Updated list of applicable CPT codes:<ul style="list-style-type: none"><li>○ Added 0512T and 0513T (<i>annual code edits</i>)</li><li>○ Removed 28899</li></ul></li><li>• Archived previous policy version SURGERY 021.25 T2</li></ul>

## INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.