MEDICAL POLICY

EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT)

Policy Number: 2014T0269P
Effective Date: July 1, 2014

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Related Policies: Lithotripsy for Salivary Stones

INSTRUCTIONS FOR USE
This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee’s document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee’s specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines 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.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage.
COVERAGE RATIONALE

Extracorporeal shock wave therapy (ESWT), whether low energy, high energy or radial wave, is unproven and not medically necessary for 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 and 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.

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

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit 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 claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

<table>
<thead>
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<th>CPT® Code</th>
<th>Description</th>
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<tr>
<td>0019T</td>
<td>Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy</td>
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<tr>
<td>0101T</td>
<td>Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy</td>
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<tr>
<td>0102T</td>
<td>Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle</td>
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<tr>
<td>0299T</td>
<td>Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound</td>
</tr>
<tr>
<td>0300T</td>
<td>Each additional wound (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>28890</td>
<td>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</td>
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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

Extracorporeal Shock Wave Therapy: Medical Policy (Effective 07/01/2014)

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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), 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.

**CLINICAL EVIDENCE**

**Achilles Tendonitis**

The clinical evidence was reviewed on April 1, 2014 with no additional information identified that would change the unproven and not medically necessary conclusions.

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.

**National Institute for Health and Clinical Evidence (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 Achilles tendinopathy 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.

**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 Tendonitis 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.

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.

Ho, (2007) conducted a technology assessment of RCTs evaluating the safety and efficacy of ESWT for treatment of chronic rotator cuff tendonitis was performed for the Canadian Agency for Drugs and Technologies in Health (CADTH). He concluded that some evidence was found to support the use of high-energy ESWT for chronic calcific rotator cuff tendonitis. However, it was stated that more high-quality RCTs with larger sample sizes are required to provide more convincing evidence.

Chronic Plantar Fasciitis (including plantar fibromatosis and plantar nerve lesion)
Plantar fasciitis is an overuse injury resulting in inflammation of the plantar fascia, which connects the heel to the toes. It is a common cause of heel pain in adults.

The safety and effectiveness of ESWT for the treatment of plantar fasciitis have been evaluated in technology assessments, meta-analyses, and randomized controlled trials (RCTs). Most studies included only patients who had had symptoms for 6 months or longer, and some specified that certain types or a minimum number of conservative treatments must have been tried. There
were some variations in technique. Double blinding was observed in most studies. A 3-month clinical endpoint was typical. Pain was the chief outcome assessed, most commonly by the Roles and Maudsley scoring system or a variation of it.

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 limitation include the lack of consistency in outcome measure, specified dose intensities and follow-up.

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).

The studies below have been grouped as low energy (LE) ESWT if the energy was less than or equal to 0.12 mJ/mm² or was adjusted to this level due to pain intolerance, and high energy (HE) if the energy was greater than 0.12 mJ/mm², according to Speed (2004). Another type of ESWT is radial pressure wave therapy which uses a simple mechanical hammer to apply shock waves to superficial skin layers only.

The ECRI Institute issued an evidence report on the use of ESWT for the treatment of plantar fasciitis in 2006. The evidence included RCTs and case series with a total of 2,233 patients. Only four trials that used a single high-energy treatment met inclusion criteria for the 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. ECRI could not reach an evidence-based conclusion regarding 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. ECRI 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 issued in 2011 stated that these conclusions remain valid (ECRI, 2011).

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.

Results reported by Haake et al. (2003) offer a better picture of the clinical significance of improvement. Less than half of patients in both groups had good or excellent Roles and Maudsley scores at 3 months. Approximately a third of patients in both groups had clinical success. The authors concluded that ESWT had offered no clinically meaningful benefit in this group of patients, but the 1-year results may have been confounded by the greater rate of subsequent secondary treatment in the placebo group.

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. Only one study by Ogden et al. (2004a) used an intention-to-treat analysis. Losses to follow-up ranged from negligible to 4% for the 3 months evaluation, were approximately 14% for the 6-month evaluation, and ranged from 27% to 56% for the 1-year follow-up.

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.

The clinical significance of the treatment effect of HE-ESWT was also questioned in a review. Buchbinder concluded that 6 RCTs of ESWT did not provide substantive support for its use for plantar fasciitis because 3 RCTs, Buchbinder et al. (2002), Haake (2003), Speed et al. (2002) showed no benefit, two others Ogden (2001) and Buch et al. (2002) reported small benefits of questionable clinical importance, and only one with 45 participants reported a significant reduction in pain at six months after treatment Buchbinder (2004).

A prospective randomized double-blind study by Gollwitzer et al. (2007) evaluated the use of ESWT in 40 patients with chronic heel pain. Pain was of at least 6 months duration and was resistant to conservative treatment. Patients were evenly divided and randomly assigned to receive either extracorporeal shockwave therapy (0.25 mJ/mm2) or sham shockwave therapy. Both groups received 3 applications of 2000 shockwave impulses, each session 1 week apart. Follow-up evaluations were performed at 6 and 12 weeks after the last intervention session. Outcomes were measured by visual analog scale (VAS) and physical examination. In the ESWT group, composite heel pain VAS score was reduced by 73.2% compared to 40.5% in the placebo group. The authors concluded that these results support the use of ESWT to treat refractory plantar heel pain. The study is limited by small sample size and short term follow-up.

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/mm2 to 0.32 mJ/mm2) (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.

In a randomized comparative trial by Hammer et al. (2003), HE-ESWT appeared to be more effective than the benefit provided by both heel cups and pharmacological treatment, but because patients were not blinded to the treatment and the study was controlled only during the first 3 months of the trial, reporting bias is likely. The comparison group continued with 3 months of
pharmacological treatment and then received ESWT according to the same protocol as the intervention group. Both groups showed dramatic and statistically significant improvement in simple pain scores at 3-months follow-up after ESWT, whereas the 3 months of continued conservative drug therapy was ineffective. The 3-month period of continued standard treatment in the comparison group indicated no spontaneous recovery. Pain scores at last follow-up (slightly over 2 years) were significantly lower compared with baseline levels in both groups. The study used only evaluated pain scores; objective outcome measures, such as changes in inflammation or thickness of the affected fascia or the use of pain medication, were not evaluated.

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/mm²) 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 that 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 (P<0.003). 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.

Rompe et al. (2003) found that 60% of ESWT patients and only 27% of placebo patients experienced at least a 50% reduction in first morning walking pain at 6 months. Rates were 72% and 35%, respectively, at 1 year, with differences remaining statistically significant. Additional treatment was permitted after 6 weeks but the frequency was not reported; this is a potential confounder. Patients gave themselves mean scores of 1.9 (ESWT group) and 2.7 (placebo group) at 1 year on a scale of excellent =1 to poor =4 overall outcome; group differences were significant. On a heel-specific functional scale, results were significantly better at 6 months and 1 year in the intervention group. The study did not use an intent-to-treat analysis and the success of patient blinding was not confirmed. Furthermore, 27% of patients in the ESWT group and 13% in the placebo group were lost to follow-up.

Three case series demonstrated reductions in pain after treatment with ESWT. Norris et al. (2005) analyzed the results of 353 patients treated with a dosage of 1,300 mJ/mm². Hyer et al. (2005) evaluated the results of 30 patients (39 heels) treated with a total dosage of 1300 mJ/mm². Wilner et al. (2004) evaluated the results of 264 patients treated with a dosage of 1800 shock waves at 18 kilovolts, 4 Hz per second. Weaknesses of these studies were the case series design, lack of control groups, differing dosage measurements and outcomes assessed by subjective questionnaires.

**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/Organizations:
National Institute for Health and Clinical 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)

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 Michaïlov, 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.

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)
The clinical evidence was reviewed on April 1, 2014 with no additional information identified that would change the unproven and not medically necessary conclusions.

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, avoiding activity that hurts, and, as healing occurs, strengthening exercises.

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.

Studies typically identified a 3-month primary clinical endpoint. Four studies also provided 1-year
follow-up data, Haake et al. (2002a), Mehra et al. (2003) Melikyan et al. (2003), Pettrone and McCall (2005). Pain was the chief outcome assessed. Nearly all studies included visual analog scale (VAS) patient ratings of pain; many studies also used the Roles and Maudsley scoring system. Four studies generally reported positive results regarding the short-term pain-relieving efficacy of active ESWT versus minimal-dose ESWT or sham treatment, Pettrone and McCall (2005), Rompe et al. (1996a, 1996b, 2004).

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 followup 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 followup 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).

Only one study, Crowther et al. (2002) (n=93) compared ESWT with another form of conservative therapy. In this study, the comparison group received a single steroid injection. At 3 months, these patients had significantly better pain scores and were significantly more likely to have experienced a 50% reduction in pain than the patients treated with ESWT. The patients treated with steroid injections were also much less likely to be referred for surgery. A high rate (40%) of withdrawal in the steroid group after randomization and before treatment limited conclusions.
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."

**National Institute for Health and Clinical 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**
The clinical evidence was reviewed on April 1, 2014 with no additional information identified that would change the unproven and not medically necessary conclusions.

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.

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 (≥95%) epithelialization (CE) for patients that did and did not undergo ESWT was 9.6 ± 1.7 and 12.5 ± 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 +/- 2.0 days and 16.7 +/- 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.

Schaden et al. (2007) evaluated the use of ESWT in 208 patients with complicated, non-healing, acute and chronic soft tissue wounds. Treatment consisted of debridement, out-patient ESWT (every 1 to 2 week over a mean of 3 treatments), and moist dressings. Thirty-two (15.4 %) patients dropped out of the study following first ESWT and were analyzed on an intent-to-treat basis as incomplete healing. Of 208 patients continuing in the study, 156 (75 %) had 100 % wound epithelialization. During mean follow-up period of 44 days, there was no treatment-related toxicity, infection, or deterioration of any ESWT-treated wound. The authors concluded that the ESWT strategy is feasible and well-tolerated by patients with acute and chronic soft tissue wounds. They also noted that ESWT is being evaluated in a phase III trial for acute traumatic wounds.
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 U.S. Food and Drug Association (FDA) classifies lithotripter devices as Class III devices, which are regulated under the premarket approval (PMA) process.

There have been no FDA approvals of ESWT devices for treatment of calcific tendonitis of the shoulder.

A number of ESWT devices are currently approved by the FDA. The OssaTron® lithotripter (HealthTronics, Marietta, GA) is an electrohydraulic, high-energy device, approved for treatment of plantar fasciitis and lateral epicondylitis that have failed conservative treatment after six months. The Epos™ Ultra high-energy device (Dornier Medical Systems, Germering, Germany), uses electromagnetic energy to generate shock waves and is approved for the treatment of chronic plantar fasciitis. The SONOCUR® Basic (Siemens, Erlangen, Germany), a low-dose electromagnetic delivery system, is approved for the treatment of chronic lateral epicondylitis. More recent FDA-approved devices for the treatment of plantar fasciitis include the Orthospec™ (Medispec Ltd, Germantown, MD) and the Orbasone Pain Relief System (Orthometrix, Inc., White Plains, NY). Both are electrohydraulic devices which utilize the spark gap method to create a shock wave. The EMS Swiss Dolorclast® (Electro Medical Systems [EMS], North Attleboro, MA) was granted premarket approval (PMA) by the FDA on May 8, 2007. Indications for use of this device are chronic proximal plantar fasciitis, in patients age 18 and older, with symptoms for six months or more, and a history of unsuccessful conservative therapy.

The OssaTron® lithotriptor (HealthTronics Inc.) was approved by the FDA for chronic proximal plantar fasciitis on October 12, 2000. The OssaTron was later approved (March 14, 2003) for chronic lateral epicondylitis. The manufacturer of the OssaTron has discontinued the device, and it is no longer available for purchase. Additional information available at: [http://www.accessdata.fda.gov/cdrh_docs/pdf/p990086a.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf/p990086a.pdf). Accessed on March 26, 2014.


No ESWT devices have been approved by the FDA for the treatment of wounds. Clinical studies under FDA approved Investigation Device Exemption (IDE) protocol are ongoing.
SoftWave Pulsed Percussion System (Tissue Regeneration Technologies, LCC, GA) is registered as a class I device with the product code ISA (therapeutic electric massager).

A number of other ESWT devices are approved by the FDA for treatment of urolithiasis, but these devices cannot be marketed for orthopedic applications, and their use for orthopedic conditions is considered "off label."

**Additional Products**
Minilith SL1, Orthowave® and Piezoson® 300, Reflectron® Evotron®, dermaPACE®, ActiVitor-Derma®

**CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)**

Medicare does not have a National Coverage Determination (NCD) for Extracorporeal Shock Wave Therapy (ESWT). Local Coverage Determinations (LCDs) do exist. Refer to the LCDs for Extracorporeal Shock Wave Therapy (ESWT), Noncovered Services, Services That Are Not Reasonable and Necessary and Non-Covered Services. (Accessed April 2, 2014)

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| 07/01/2014 | • Reorganized policy content  
  • Added benefit considerations language for Essential Health Benefits for Individual and Small Group plans to indicate:  
    o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits (“EHBs”)  
    o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans  
    o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee’s specific plan document to determine benefit coverage  
  • Updated coverage rationale; added language to indicate the unproven service is “not medically necessary”  
  • Updated supporting information to reflect the most current clinical evidence, FDA and CMS information, and references  
  • Archived previous version 2013T0269O |