

EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT)

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[Instructions for Use](#) ⓘ

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Related Medical Management Guideline
• Lithotripsy for Salivary Stones

COVERAGE RATIONALE

Extracorporeal shock wave therapy (ESWT), whether low energy, high energy or radial wave, is unproven and not medically necessary for all indications, due to insufficient evidence of efficacy.

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 guideline 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 and Guidelines 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
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), also referred to as extracorporeal shock wave lithotripsy (ESWL). ESWT is a noninvasive treatment that uses the force of an acoustic shock wave with the goal of reducing pain and promoting healing of the affected area. The mechanism by which ESWT achieves a therapeutic intervention in orthopedic conditions is not completely understood, but there are several hypotheses. ESWT may disrupt fibrous tissue allowing for the subsequent promotion of revascularization and healing of tissue. Also, it is believed that the direct and indirect effects of the shock waves may damage cell membranes so that nociceptors cannot build up a

potential to transmit pain signals. It is thought that the shock waves will break up these deposits, loosen structures, promote resorption of calcium, thereby decreasing pain and improving function. (Hayes 2016a).

CLINICAL EVIDENCE

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.

Professional Societies / Technology Assessments

Health Technology Assessment (HTA)

A 2017 Health Technology Assessment (HTA) reviewed the evidence for the efficacy of ESWT for treating Achilles tendinopathy. Two small RCTs showed significant pain improvement while running or playing sports, but there was no difference between groups while working or using the stairs. One RCT reported significant improvement in function when comparing ESWT to sham. The strength of evidence for this indication was low and there was no evidence found on the intermediate or long term outcomes.

National Institute for Health and Clinical Evidence (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.

Calcific Tendonitis of the Shoulder (Rotator Cuff)

Wu et al. (2017) performed a systematic review and network meta-analysis (n=14 RCTs/1105 patients) to investigate the effectiveness of non-operative treatments for chronic calcific tendinitis of the shoulder. Study participants were adults diagnosed with clinical symptoms related to calcific tendinitis of the shoulder confirmed by radiologic or ultrasound examination, and unresponsive to initial conservative treatment. The outcomes evaluated were improvement in the pain severity, functional status of the shoulder, and the resolution of calcific deposits. Follow-up in studies primarily ranged from three-12 months. Acknowledged limitations of the analysis include the lack of a no-treatment group and the high heterogeneity of outcomes between studies. The authors noted that the latter could be due to differences in protocols used for treatment, number of pulses, frequency of treatment, as well as the variable range of energy levels (energy flux density), and different ultrasound-guided approaches. Individual studies were also limited by small sample sizes and short-term follow-up.

Bannuru et al. (2014) conducted a systematic review (n=28 RCTs/1307 subjects) of the evidence to assess the efficacy of ESWT in patients with calcific and non-calcific tendinitis. The outcome measures included pain, function and calcification resolution which was evaluated only in calcific tendinitis trials. High-energy ESWT was found to be statistically significantly better than placebo for both pain and function. The results for low-energy ESWT favored ESWT for function, while results for pain were inconclusive. The reduction in calcification was significantly greater after high-energy ESWT than after placebo treatment; results for low-energy ESWT were inconclusive. Evidence suggesting a benefit of ESWT for non-calcific tendinitis was also inconclusive. Limitations were heterogeneity and size of the included trials. Larger controlled randomized trials as well as standardization of energy levels and treatment protocol are needed to further define the role of ESWT for treating calcific tendinitis of the shoulder.

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.

Professional Societies/Technology Assessments

Health Technology Assessment (HTA)

A 2017 Health Technology Assessment (HTA) reviewed the evidence for the efficacy of ESWT for treating shoulder tendinopathies. Two trials showed that treatment with ESWT showed greater improvement in pain outcomes when compared to sham over all time frames (low and moderate quality studies). Several other studies indicated no significant improvements in pain outcomes across all timeframes. Results for functional outcomes were inconsistent with low and moderate quality studies showing improvement in function with ESWT compared to sham or active control with the majority of studies showing no difference between groups.

According to the NICE guidance on the use ESWT for calcific tendonitis of the shoulder, current evidence on the safety and efficacy appears adequate to support the use of the procedure provided that normal arrangements are in place for consent, audit, and clinical governance (NICE, 2003; 2012c).

Chronic Plantar Fasciitis (including plantar fibromatosis and plantar nerve lesion)

Lai et al. (2018) published the results of a prospective randomized controlled trial which evaluated and compared the therapeutic effects of ESWT and corticosteroid injections (CSI) in patients with chronic plantar fasciitis. The study also examined the correlation between plantar fascia thickness changes and clinical outcomes. Patients were included if they had more than two months without an injection and had been treated with conservative treatment for one month, without improvement before proceeding to ESWT or CSI treatment. Patients (110) were randomly assigned to receive ESWT or CSI. The authors summarized that extracorporeal shockwave therapy (ESWT) was more efficient in reducing chronic fasciitis pain after 12 weeks than corticosteroid injection. Furthermore, the increase in plantar fascia thickness after ESWT, the more efficient the clinical outcome. However, further long term studies with large patient populations are needed to validate the findings of this study.

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. 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 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)

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.

Gerdsmeyer 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% , and an overall success rate of 61.0% compared with 42.2% in the placebo group 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 . 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 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 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 ESWT as a third tier treatment 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)

The 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.

Canadian Agency for Drugs and Technologies in Health (CADTH)

A 2016 report issued by the Canadian Agency for Drugs and Technologies in Health (CADTH) reviewed evidence 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).

Health Technology Assessment (HTA)

A 2017 Hayes health technology assessment (HTA) reviewed the evidence for the efficacy of ESWT for treating plantar fasciitis. A pooled analysis was completed with five high quality studies which showed that short-term pain outcomes were significantly better in the ESWT group compared to a sham group. There were inconclusive results in intermediate and long-term pain outcomes. One study found no difference between groups for functional outcomes and one low quality study showed that ESWT had greater improvement in function compared to sham. The HTA reported insufficient and low quality evidence across the studies comparing ESWT to active control groups for both pain and functional outcomes.

Delayed or Nonunion Fractures

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)

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).

Aydin and Atiç (2018) performed a prospective randomized controlled trial comparing the efficacy of ESWT to wrist-extensor splint (WES) application in the treatment of lateral epicondylitis (LE). Patients were included if they had been treated based on a diagnosis of unilateral LE. Patients were excluded if they had bilateral LE, carpal tunnel syndrome, cubital tunnel syndrome, previous elbow surgery, previous conservative and surgical treatment for LE, neurological deficits in the upper extremity, systemic disease, other diseases in the neck and shoulder region, lateral epicondylar tendon ruptures, tumors in the forearm and elbow, osteoporosis, and hemophilia. The patients were randomized into two groups. Group one received ESWT four times per week using the DolorClast device and group two received a wrist extensor splint. The primary outcomes measured were the effectiveness of ESWT compared to WES in decreasing pain, improving grip strength, increasing quality of life, and alleviating arm pain during daily life activities in the treatment of LE. Evaluation data were collected before and after treatment at weeks four, 12, and 24. In both groups there were significant improvements in decreasing pain, increasing grip strength and improving quality of life at four, 12, and 24 weeks compared to pretreatment values. However, there was no statistically significant difference between the two groups at the three time points. The authors noted limitations of the study were the small patient population and use of the patient-reported questionnaires.

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.

Professional Societies/Technology Assessments

The 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.

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."

Health Technology Assessment (HTA)

A 2017 Health Technology Assessment (HTA) reviewed the evidence for the efficacy of ESWT for treating lateral epicondylitis. In two studies patients receiving ESWT were two times as likely to achieve $\geq 50\%$ improvement over baseline in the short-term compared with those receiving sham. There is no evidence for intermediate or long term wrist extension pain outcomes. Further, there is not enough evidence from three small studies to determine the effect of ESWT vs. sham on other non-specified pain outcomes over any timeframe. There was significant improvement in short-term function in two studies however there was no difference after 12 months of follow-up.

National Institute for Health and Clinical Excellence (NICE)

A NICE guidance on the use of ESWT for refractory tennis elbow states that the evidence on ESWT for refractory tennis elbow raises no major safety concerns; however, current evidence on its efficacy is inconsistent. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE, 2009d; 2012d).

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

A 2019 Hayes prognosis overview evaluated the evidence for the efficacy of ESWT with dermaPACE system for treating diabetic foot ulcers (DFUs). The best available evidence is a single published report on 2 randomized, sham controlled trials of dermaPACE in patients with DFU; both trials failed to meet the primary efficacy endpoint of complete wound closure at 12 weeks. There is insufficient published evidence to assess whether the addition of ESWT with the dermaPACE system significantly expedites wound healing in patients with DFUs.

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 ± 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.

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.

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 randomised 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.

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 12, 2019)

REFERENCES

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GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
06/01/2019	Supporting Information <ul style="list-style-type: none">Updated <i>Description of Services, Clinical Evidence, and References</i> sections to reflect the most current information; no change to coverage rationale or list of applicable codesArchived previous policy version MMG043.L

INSTRUCTIONS FOR USE

This Medical Management Guideline provides assistance in interpreting UnitedHealthcare 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 benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Management Guideline is provided for informational purposes. It does not constitute medical advice.

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Member benefit coverage and limitations may vary based on the member's benefit plan Health Plan coverage provided by or through UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare Benefits of Texas, Inc., or UnitedHealthcare of Washington, Inc.