

Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds (for Kentucky Only)

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[➔ Instructions for Use](#)

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Related Policy
<ul style="list-style-type: none"> Lithotripsy for Salivary Stones (for Kentucky Only)

Application

This Medical Policy only applies to the state of Kentucky.

Coverage Rationale

For medical necessity clinical coverage criteria for extracorporeal shock wave therapy (ESWT), high energy, for plantar fasciitis, refer to the InterQual® CP: Procedures, Plantar Fasciitis, Extracorporeal Shock Wave Therapy (ESWT).

Click [here](#) to view the InterQual® criteria.

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

Note: This policy does not address Extracorporeal Shock Wave Lithotripsy (ESWL) used for the treatment of:

- Gallstones
- Kidney stones
- Pancreatic stones
- Salivary stones

Applicable Codes

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

require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified
0102T	Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving the lateral humeral epicondyle
0512T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; initial wound
0513T	Extracorporeal shock wave for integumentary wound healing, 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) devices are similar to the lithotripters used for breaking up kidney stones in urology. They produce low- or high-energy pulses arising from acoustic energy, called shock waves, which can be focused and then propagated through water within body tissues. When focused on a boundary between tissues of differing densities, the shock wave is altered, and energy is emitted. The shock waves for orthopedic indications are the same as those used to break up kidney stones, but have ten times less energy. Low energy defocused ESWT or soft focused acoustical wave pattern is used for wound healing.

Although the mechanism of therapeutic effect for ESWT has not been established, it has been proposed that shock waves may have a direct mechanical effect through the rapid buildup of positive pressure and/or a more indirect effect through the implosion of bubbles in the interstitial fluid. These forces may reduce transmission of pain signals from sensory nerves, cause calcium deposits to disintegrate, break down scar tissue, cause a transient inflammatory response, and/or stimulate tissue healing (Hayes 2022).

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.

Feeney (2022) conducted a systematic review to evaluate the use of ESWT in the management of midportion Achilles tendinopathy. A search of databases (MEDLINE (PubMed), AMED, EMBASE, CINAHL, and CENTRAL) was performed with a total of 283 articles identified. Of these, seven randomized controlled trials (RCTs) were eligible for inclusion in the review. The mean sample size of the included studies was 57. Five studies diagnosed midportion Achilles tendinopathy based on history and physical examination while two confirmed the presence of Achilles tendinopathy by combining history and physical examination with ultrasound findings. Three studies utilized radial ESWT only, one study used a combination of radial and focused ESWT, one study compared radial and focused ESWT, and two studies used focused ESWT only. The length of follow-up ranged from three to 16 months. Overall, four of the seven RCTs included found a statistically significant improvement in outcome measures with the use of ESWT compared to control. The other three studies observed no statistically significant improvement in outcome measures with the use of ESWT compared to control, each did observe a significant improvement in the ESWT groups from baseline. The author concluded ESWT appeared to be safe and at least as effective as control in the management of Achilles tendinopathy. Additionally, the most effective intervention may be a combination of eccentric loading

exercises with a course of ESWT. The author suggests that further high-quality studies with larger sample sizes and a combination of treatments are needed to determine the most effective treatment, dose, time between treatments, and frequency (Hz) of ESWT patients should receive.

In 2019, Stania et al. published results from a systematic review of research reports on ESWT in patients with Achilles tendinopathy to help practicing physiotherapists establish the most effective intervention parameters. A search was conducted using the following databases: PubMed, Scopus, EBSCOhost, and Web of Science. The papers were checked for relevant content and were included based on the following criteria: full-text article published in English and including comprehensive description of shock wave application. Twenty-two articles met the inclusion criteria. Most studies on the effectiveness of ESWT for Achilles tendinopathy included in this review were RCTs. Two case-control studies, a case series study, prospective audit, clinical trial protocol, and a pilot study were also considered. The majority were prospective studies. Only a few authors presented the findings from retrospective observations. The two modalities of shock wave therapy used for Achilles tendinopathy are focused shock waves and radial shock waves. The authors concluded that the complexity of the biological response to shock waves, the high diversity of application methodologies, and the lack of objective measurements all prevent ESWT effectiveness for Achilles tendinopathy from being fully determined. There are knowledge gaps yet to be researched, and the results of experimental studies remain contradictory. The authors noted that there is a need for further multidirectional and multicenter, randomized controlled studies on the effectiveness of shock waves for Achilles tendinopathy that should fulfil the criteria for evidence-based medicine.

A 2017 Health Technology Assessment, contracted by the Washington State Health Care Authority, 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.

Guidance from the National Institute for Health and Care Excellence (NICE) concluded that although the evidence on extracorporeal shockwave therapy for refractory Achilles tendinopathy raises no major safety concerns, evidence on efficacy of the procedure is inconsistent. 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 anesthesia and the type and duration of energy applied. Studies should include validated outcome measures and have a minimum of one year of follow-up (NICE, 2016).

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 RCTs of ESWT for Achilles tendinopathy are contradictory, but that there is at least some evidence for short-term improvements in function with ESWT.

Calcific Tendonitis of the Shoulder (Rotator Cuff)

Review of the recent clinical evidence suggests that, based on conflicting findings, high-energy ESWT is promising but not yet proven for improving pain and shoulder function in clinically significant ways for some patients with chronic calcific shoulder tendinitis; additional standardization of energy levels and treatment protocols are needed as well as additional data to address safety concerns and assess in which patient population benefits outweigh harm.

A Hayes Health Technology Assessment (2022) evaluated the efficacy of ESWT for treating symptomatic calcific tendinitis of the shoulder when conservative therapies have failed. Twelve RCTs were included in the assessment. ESWT was associated with improvement in function from baseline and reduction of pain in some patients with calcific tendinitis of the shoulder. Evidence comparing ESWT with clinical alternatives yielded conflicting findings or was limited in quantity. Primary complications were pain or discomfort during or just after treatment, bruising, and swelling. Hayes noted the overall quality of evidence was low and while ESWT appears to be safe and effective, continued research is needed to determine optimal ESWT treatment parameters, clarify comparative benefit versus alternative treatments, and establish treatment durability. Follow-up beyond twelve months was also recommended.

According to the NICE guidance on the use of ESWT for calcific tendonitis of the shoulder, current evidence shows no major safety concerns in the short-term. However, evidence on efficacy is noted as inadequate. NICE recommends that ESWT for calcific tendinopathy in the shoulder should only be used in the context of research and further research should include RCTs comparing the procedure with current best practice (NICE, 2022).

Shao et al. (2022) conducted a RCT to investigate the effect of ESWT on short-term functional and structural outcomes after rotator cuff repair. Two groups randomized to either the ESWT group (n = 19) or the control group (n = 19) participated in five weeks of advanced rehabilitation three months after rotator cuff repair. The ESWT group also received 2000 pulses of shockwave therapy once a week for five weeks. All individuals had clinical and magnetic resonance imaging (MRI) examinations at three months (baseline) and at six months (follow-up) after surgery. Thirty-two participants completed all assessments. Pain and function improved in both groups. At six months post repair, pain intensity was lower and American Shoulder and Elbow Surgeons form scores were higher in the ESWT group than in the control group (all p-values < 0.01). Signal/noise quotient near the suture anchor site decreased significantly from baseline to follow-up in the ESWT group (p = 0.008) and was significantly lower than that in the control group (p = 0.036). Muscle atrophy and the fatty infiltration index did not differ between groups. The authors concluded radial ESWT reduced early shoulder pain and accelerated proximal supraspinatus tendon healing at the suture anchor site post rotator cuff repair. However, the authors note that in terms of functional outcomes at the short-term follow-up, radial ESWT does not appear to be superior to advanced rehabilitation. Limitations include small sample size, short follow-up period, and the study only included individuals with medium to large rotator cuff tears. The authors suggest further studies are needed to evaluate the correlation between energy flux density and biological effects.

Surace et al. (2020) reviewed thirty-two RCTs and controlled clinical trials involving 2281 participants with rotator cuff disease with or without calcific deposits. The primary comparison was shock wave therapy compared to placebo with a 3-month follow-up. The findings favored ESWT vs. placebo for pain levels (standardized mean difference -0.49, 95% CI -0.88 to -0.11) and functional status (standardized mean difference 0.62, 95% CI 0.13 to 1.11). The adverse events were more frequent with ESWT than placebo (relative risk 3.61, 95%CI 2.00 to 6.52). The authors concluded there were very few clinically important benefits of ESWT and uncertainty regarding its safety based on the currently available low- to moderate-certainty evidence.

Testa et al. (2020) completed a systematic review of two electronic medical databases searching for studies on the use of ESWT therapy without surgical treatment with symptoms duration more than two months, and at least six months of follow-up for treating rotator cuff tendinopathy, subacromial impingement, and medial and lateral epicondylitis. After screening 822 articles that met the initial criteria, 26 articles were selected that met their criteria after a full-text review. The authors concluded that ESWT is a safe and effective treatment of soft tissue diseases of the upper limbs. Even in the minority cases when unsatisfied results were recorded, high energy shockwaves were nevertheless suggested in prevision of surgical treatment. The authors however reported a moderate overall risk of bias that could have influenced their analysis.

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. No significant benefit was found between ESWT and placebo for non-calcific tendinitis. The authors concluded that high-energy ESWT is effective for improving pain and shoulder function in chronic calcific shoulder tendinitis and can result in complete resolution of calcifications.

Verstraelen et al. (2014) conducted a systematic review and meta-analysis of RCTs across five electronic online databases to identify all RCTs that compared high-energy ESWT (> 0.28 mJ/mm²) with low-energy ESWT (< 0.09 mJ/mm²) in treating patients with calcifying rotator cuff tendinitis. The literature search originally identified 194 potentially relevant studies; 189 of which were screened out as they did not meet the criteria for the analysis. The total study population from five RCT's of low-versus high-energy ESWT consisted of 359 participants. All five RCTs showed greater improvement in functional outcome (Constant-Murley score) in patients treated with high-energy ESWT compared with patients treated with low-energy ESWT at three and six months. The three month mean difference was 9.88 (95% CI, 9.04–10.72, p < 0.001; 6-month data could not be pooled). Furthermore, high-energy ESWT more often resulted in complete resorption of the deposits at three months. The corresponding odds ratio was 3.40 (95% CI, 1.35–8.58) and p = 0.009 (six month data could not be pooled). Based on the meta-analysis, the authors concluded that high-energy ESWT is more effective than low-energy ESWT in terms of functional outcome

(Constant-Murley score) and radiographic resorption (chance of complete resorption) of the deposits after three months. However there is still a need for high-quality RCTs to discover the exact dose-response relation. In the authors' opinion, this future research should focus on high-energy ESWT because current available evidence indicates that high-energy ESWT is more effective than low-energy ESWT regarding the functional and radiologic outcomes in the short term and midterm.

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 six months with ESWT over placebo. However, most studies were considered to be low quality.

Huisstede et al. (2011) performed a systematic review of RCTs examining the effectiveness of ESWT as a treatment alternative for calcific and non-calcific rotator cuff tendinosis. The reviewers found that only high-ESWT (H-ESWT) is effective for treating calcific rotator cuff tendinosis. No evidence was found for the effectiveness of ESWT to treat non-calcific rotator cuff tendinosis.

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.

Clinical Practice Guidelines

Canadian Agency for Drugs and Technologies in Health (CADTH)

A 2016 report issued by the CADTH reviewed evidence on the effectiveness of shockwave therapy for pain associated with upper extremity orthopedic disorders including rotator cuff tendinopathy and epicondylitis. Evidence from four systematic reviews suggests that, in comparison with placebo, shockwave therapy using high energy is effective in reducing pain in calcific tendinitis of the shoulder. Evidence suggests that there is no significant benefit with ESWT compared to placebo or other treatments in case of non-calcific tendinitis of the shoulder. It should be noted however, that there is considerable overlap in the studies included in the four systematic reviews, hence findings are not mutually exclusive. The authors noted it appears that in general, the techniques for using SWT for all orthopedic disorders still need to be standardized. There appears to be a lack of consensus regarding the definitions for high and low energy SWT. Other issues include determination of precise doses and optimal frequency of application, whether the shockwaves should be directed to the target area by radiological or ultrasound imaging, and whether local anesthetic injections should be used in the target area prior treatment to reduce pain (CADTH, 2016).

Delayed or Nonunion Fractures

Conclusive evidence recommending ESWT as an effective treatment for delayed or nonunion fractures is lacking.

A systematic review was completed by Kwok et al. (2022) to evaluate the use of ESWT in the treatment of foot and ankle fracture non-unions. Four databases were searched to identify relevant studies in the available literature. Eight studies were reviewed, demonstrating union rates of 65%-100% and 90-100% at 3- and 6-months following ESWT treatment, respectively. No major complications were seen in any of the studies. Minor complications included local soft tissue swelling, petechiae, bruising and pain. The authors concluded that the literature that is currently available is limited to case series of relatively small sample sizes, highlighting the need for a prospective, RCTs to further investigate the efficacy of ESWT in the treatment of foot and ankle fracture non-unions.

In a systematic review by Willems et al (2019) evaluating ESWT for treatment of delayed or non-union fractures, the authors found that high quality RCTs are still needed to validate the efficacy and safety of this treatment. The review included 30 peer reviewed studies consisting of two RCTs and 28 prospective and retrospective cohort studies involving a total of 2027 delayed-unions and nonunions in adults. Delayed-unions treated with ESWT had a union rate of 86% (n = 314) while nonunions treated with ESWT had a 73% (n = 1782) overall union rate. The overall union rate of nonunions treated with surgery was 81% (n = 80). Although the results showed similar union rates between ESWT and surgery-treated patients, none of the ESWT group had adverse events that required further care while there were severe adverse events noted in the surgery group. The authors found a lot of heterogeneity within and between the studies such as fractures of different bones, the use of different energy settings, number of treatments and number of shock waves applied with the ESWT and a lack of consensus as to when the biological endpoint is reached in which no further bone healing occurs. The authors concluded that high quality RCTs should be

conducted on the effect of ESWT with homogeneous groups and shock wave parameters so that treatment recommendations can be made.

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% and 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 one to three 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 RCT by Cacchio et al. (2009) compared ESWT 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 six, 12 and 24 months. The authors concluded that ESWT 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 ESWT for the treatment of hammer toe.

Lateral Epicondylitis (Tennis Elbow)

Evidence in the form of RCTs regarding the efficacy of ESWT for lateral epicondylitis (LE) is conflicting and inconsistent.

A systematic review and network meta-analysis by Liu et al. (2022) was completed to examine the efficacy of ESWT and injection therapies by synthesizing direct and indirect evidence for all pairs of competing therapies for LE. PubMed, EMBASE, and Web of Science databases were searched for all appropriate RCTs, assessing the effect of ESWT or injection therapies. The primary outcome was short-term (≤ 3 months) and medium-term (> 3 months but ≤ 12 months) pain, while the secondary outcomes were grip strength and patient-reported outcome measures. All outcomes were assessed using standardized mean differences (SMDs) with 95% confidence intervals and were ranked using surface under the cumulative ranking curve (SUCRA) probabilities to determine a hierarchy of treatments. Sensitivity analysis was performed to eliminate potential therapeutic effects of normal saline (NS) and exclude trials that included patients with acute LE. Results: 40 RCTs were included to evaluate ESWT and five different injection therapies, including corticosteroids, autologous whole blood, platelet-rich plasma, botulinum toxin A (BoNT-A), and dextrose prolotherapy (DPT). DPT (-.78 [-1.34 to -.21]), ESWT (.57 [-.89 to -.25]), platelet-rich plasma (-.48 [-.85 to -.11]), and BoNT-A (-.43 [-.84 to -.02]) outperformed placebo for short-term pain relief; ESWT (-.44 [-.85 to -.04]) outperformed placebo for medium-term pain relief. DPT was ranked as the most optimal short-term and medium-term pain reliever (SUCRA, 87.3% and 98.6%, respectively). ESWT was ranked as the most optimal short-term and medium-term grip strength recovery (SUCRA; 79.4% and 86.4%, respectively). The authors concluded that DPT and ESWT were the best two treatment options for pain control and ESWT was the best treatment option for grip strength recovery. Corticosteroids were not recommended for the treatment of LE. More evidence is required to confirm the superiority in pain control of DPT among all these treatment options on LE. Limitations to the study included no standardized treatment protocol for each treatment, as well as no standardized

protocols and treatment modalities in ESWT. The effectiveness of ESWT may change with the evolution of the times and advancement of machines. Further research with RCTs is needed to validate these findings.

Özmen et al. (2021) performed a comparison study to determine the clinical and sonographic effects of ultrasound (US) therapy, ESWT, and Kinesio taping (KT) in LE. A total of 40 patients with LE were included in the study. The patients were randomly assigned to 3 treatment groups: US (n = 13), ESWT (n = 14), and KT (n = 13) groups. The VAS scores decreased in all groups ($p < 0.05$). Grip strength increased after 8 weeks in only the KT group ($p < 0.05$). The Patient-Rated Tennis Elbow Evaluation Scale scores significantly decreased after two weeks and after eight weeks in the US group and ESWT groups, and after eight weeks in the KT group ($p < 0.05$). Common extensor tendon (CET) thicknesses decreased after eight weeks in only the ESWT group ($p < 0.05$). The authors concluded that the US therapy, KT, and ESWT are effective in reducing pain and improving functionality. However, none of these treatment methods were found to be superior to others in reducing the pain and improving functionality. Limitations of the study include small sample size (40 patients) and short duration of follow-up. Also, there was no exercise intervention in addition to the treatment methods applied. Grip strength may be increased by strengthening the forearm muscles.

Atalay and Gezginaslan (2020) completed a RCT to evaluate the effectiveness of neural therapy (NT) versus ESWT in the treatment of LE. Between August 2018 and November 2018, 76 patients with LE (26 males, 50 females; mean age: 44, 8 ± 9.5 years; range, 29–65 years) were randomly allocated to either NT or ESWT one session weekly for a total of three weeks. The subjective pain severity was evaluated using the VAS and Duruoz Hand Index (DHI) was used to assess the functional disability before and after treatment and at 12 weeks. When the before and after treatment and 12 weeks variances of values were compared between ESWT and NT groups, there were no differences in the VAS and DHI scores between the groups ($p > 0.05$) (VAS score at 12 weeks (effect size = 0, 18, 95% confidence interval (CI): -0,358–1,619) or DHI score (effect size = 0, 13, 95 % CI: -7,627–4,390). However, within the groups, there were differences in VAS and DHI scores between before treatment and after treatment ($p < 0.05$), and between before treatment and at 12 weeks follow up ($p < 0.05$). No adverse events occurred in this study. The authors concluded that the results of this study showed that both ESWT and NT have similar effects in reducing pain and hand function in patients with LE. However neither of two the treatment modalities showed superiority. There are some limitations to this study. The number of subjects in the study is small which could have decreased the power of the study. As there was no control group, the authors could not determine the effect of two therapeutic methods. The lack of blinding, qualitative data/feedback from patients, non-treatment group or routine care group, and long-term outcomes are the other limitations of the study. Further investigation with large-scale, prospective, long-term outcomes, placebo-controlled studies are needed.

In a systematic review and meta-analysis by Yao et al. (2020), the authors found that additional high quality RCTs are still needed to validate that ESWT safely and effectively relieves the pain and functional impairment from LE. The meta-analysis included 13 published RCTs that included 1035 patients, of which 501 patients received ESWT and 534 received other treatments. Due to the heterogeneity of the studies, the authors performed a pooled analysis of the data which they concluded showed significantly lower visual analogue scale (VAS) scores ((0 indicating no pain and 10 the worst pain) indicative of early recovery and significantly increased grip strength in the ESWT treatment group. There were also several limitations of the meta-analysis identified by the authors, including different ESWT instruments, treatment protocols, diagnostic criteria and the fact that the majority of the studies were conducted in one country. The authors concluded that future RCTs should address these limitations.

Another systematic review and meta-analysis completed in 2020 by Yoon et al. focused on the effect of ESWT on LE for reducing pain and improving grip strength as well; however, the analysis also investigated the effects of ESWT according to the specific type applied, symptom duration and follow up duration. In this review, 12 studies with 1104 patients were included in the meta-analysis with ten of the 12 studies having also been included in the Yao systematic review and meta-analysis. This meta-analysis concluded that ESWT did not show clinically important improvement in pain reduction and grip strength although the authors did conclude that radical ESWT was more effective than focused ESWT and that patients with longer duration of symptoms had more improvement while the effects did not last beyond 24 weeks. Yoon et al. also noted the heterogeneity of the studies included in the review and the diversity of the treatment protocols, shock wave devices and length of treatment among the studies. The authors recommended future studies on specific conditions and parameters to establish optimal protocol settings for ESWT for LE.

Aydın and Atıç (2018) performed a prospective RCT comparing the efficacy of ESWT to wrist-extensor splint (WES) application in the treatment of 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.

A 2017 Health Technology Assessment (HTA) reviewed the evidence for the efficacy of ESWT for treating LE. 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.

Capan et al. (2016) conducted a double-blind, randomized, placebo-controlled trial in outpatient clinics of a medical faculty hospital. Fifty-six patients with LE were randomized to radial ESWT or sham radial ESWT groups. Both the patients and the outcome assessing investigator were blinded to group assignment. The radial ESWT was administered to the painful epicondyle at the elbow at each session at three once weekly sessions. Sham radial ESWT was applied without the contact of the applicator at the same area. Study patients were assessed at baseline and at one and three months after treatment using a VAS 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 radial ESWT and sham radial ESWT 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 radial ESWT does not seem to be more effective either in reducing pain or improving function or grip strength in patients with LE at least at three months after treatment when compared with sham radial ESWT.

A National Institute for Health and Care Excellence (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, 2009a).

Staples et al. (2008) conducted a double-blind, RCT on 68 patients to determine whether ultrasound-guided ESWT reduced pain and improved function in patients with LE (tennis elbow) in the short term and intermediate term. Patients were randomized to receive three ESWT treatments or three treatments at a subtherapeutic dose given at weekly intervals. Seven outcome measures relating to pain and function were collected at follow-up evaluations at six weeks, three months, and six months after completion of the treatment with mean changes compared for the two 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 LE.

Refractory Greater Trochanteric Pain Syndrome (GTPS)

There is insufficient quality evidence to conclude ESWT is effective for GTPS therefore, additional research involving larger, well-designed studies is needed to establish its safety and efficacy.

The ECRI Institute published an Executive Summary on the use of ESWT for chronic lateral hip pain/GTPS with a focus on the safety and efficacy of ESWT used with or in place of physical therapy, pain medication, and other non-surgical treatments. The review included one systematic review (n = 295) of controlled studies and two RCTs (n = 103 and n = 50) that were not included in the systematic review. The Executive Summary concluded that the evidence is inconclusive due to limited data available and the high risk of bias from the studies reviewed because of lack of randomization or complete blinding, small size, high attrition

and single-center focus. Other published data that were not included in the review were excluded because the risk of bias was higher and because there were too few patients per treatment. ECRI Institute recommended large, multi-centered studies to validate available data and to assess long term outcomes related to pain recurrence and retreatment (ECRI 2020).

Ramon et al (2020) completed a randomized, multicenter clinical trial with 103 participants with chronic GTPS. The participants were divided into two groups, both of which were treated with three weekly sessions of focused extracorporeal shockwave treatment (F-ESWT) with the test group (n = 53) receiving an energy flux density (EFD) of 0.20 mJ/mm² and the control group (n = 50) receiving the lowest EFD of the device (0.01 mJ/mm²) using the same brand of device. Each participant was assessed at baseline and one, two, three, and six months after the last session by clinicians blinded to the group allocation. The authors concluded that F-ESWT and a specific home exercise program is safe and effective for GTPS, with a success rate of 86.8% at two months after treatment that was maintained until the end of the six month follow up. Limitations identified by the authors included a lack of follow-up beyond six months, a lack of exact data on participants' compliance with the home exercise protocol, the imbalance of participation by women (n = 74) to men (n = 29) in a sample size of only 103, which may not detect important differences in responses to the intervention between the sexes and that the control group received some albeit the lowest dose of ESWT so it could be considered a quasi-placebo group. The authors recommend further high-quality RCTs to confirm the long-lasting effectiveness of F-ESWT for GTPS.

In 2015, Mani-Babu et al. reported results of a systematic review and meta-analysis of studies evaluating ESWT for lower limb tendinopathies, including greater trochanteric pain syndrome (GTPS). The review included 13 studies providing sufficient data to compute effect size calculations. The energy level, number of impulses, number of sessions, and use of a local anesthetic varied between studies. The authors concluded that there was limited to moderate evidence to support ESWT as an effective intervention and should be considered for GTPS when other nonoperative treatments have failed.

A National Institute for Health and Care Excellence (NICE) guidance on the use of ESWT for refractory greater trochanteric pain syndrome states that the evidence on ESWT for refractory greater trochanteric pain syndrome is limited in quality and quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE, 2011).

Tenosynovitis of the Foot or Ankle

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

Wounds

ESWT mechanisms of action for wound healing are not fully elucidated in the literature. The current understanding is that the mechanical effects of the shock waves on cells trigger biological responses that enhance tissue perfusion and angiogenesis.

The ECRI Institute published a Clinical Evidence Assessment on the dermaPACE System in 2020 that focused on how the device compares with standard of care and other chronic wound treatments. ECRI concluded that the evidence is somewhat favorable when comparing dermaPACE with standard of care alone as it appears to improve complete diabetic foot ulcer (DFU) healing rates at 24 week follow-up and decreases time to wound closure. ECRI based their recommendation on two low-quality RCTs (n = 206, n = 130) that were multi-centered and double blinded based on pooled data from the same study participants. ECRI also reviewed a third RCT from a single-center, open-label study (n = 77; 84 ulcers) that compared dermaPACE with hyperbaric oxygen therapy in patients with chronic DFUs and reported rates of complete wound closure, improved healing, unchanged ulcers, and adverse events. They did not find any published studies that evaluated the effectiveness of dermaPACE for treating chronic wound types other than DFUs. dermaPACE has been granted De Novo clearance by the FDA only for treating DFUs at this time although it is intended to treat chronic wounds more broadly.

Huang et al. (2020) performed a systematic review and meta-analysis of eight RCTs (n = 339) to assess the safety and efficacy of ESWT on the healing of DFUs. The authors concluded that ESWT was associated with a greater reduction of the wound surface area, an increase of re-epithelialization and more patients with complete cure at the end of treatment. All the included

studies were conducted by different medical centers in different countries with varied treatment protocols for treatment strength, frequency and duration. Patient ages ranged from 56.2 to 67.8 years. The control groups in the studies also received various treatments with standard wound care in 6 RCTs and hyperbaric oxygen therapy (HBOT) in two studies. The authors also found that ESWT was more effective than HBOT for treating DFUs. Limitations identified by the authors include the application of ESWT only to DFU wounds, the small number of included studies in the meta-analysis (< 10) and that cost effectiveness was not reviewed.

In a systematic review and meta-analysis, Zhang et al. (2018) examined the effects of ESWT and conventional wound therapy (CWT) for acute and chronic soft tissue wounds. A total of ten RCTs involving 473 patients were included in this systematic review and meta-analysis. The meta-analysis showed that ESWT statistically significantly increased the healing rate of acute and chronic soft tissue wounds 2.73-fold (OR = 3.73, 95 % CI: 2.30 to 6.04, $p < 0.001$) and improved wound-healing area percentage by 30.45 % (SMD = 30.45; 95 % CI: 23.79 to 37.12; $p < 0.001$). ESWT reduced wound-healing time by 3 days (SMD = -2.86, 95 % CI: -3.78 to -1.95, $p < 0.001$) for acute soft tissue wounds and 19 days (SMD = -19.11, 95 % CI: -23.74 to -14.47, $p < 0.001$) for chronic soft tissue wounds and the risk of wound infection by 53 % (OR = 0.47, 95 % CI: 0.24 to 0.92, $p = 0.03$) when compared with CWT alone. Serious adverse effects were not reported. The authors concluded that ESWT showed better therapeutic effects on acute and chronic soft tissue wounds compared with CWT alone. However, the authors noticed that higher-quality and well-controlled RCTs are needed to further evaluate the role of ESWT for acute and chronic soft tissue wounds.

Omar et al. (2017) performed a systematic review of ten 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 program. 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 systematic review which included three RCTs, 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 ESWT for the treatment of lower limb ulceration due to the limited evidence available.

In a phase II RCT, 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.

Wang et al. (2011) investigated the molecular changes of 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.

Larking et al. (2010) assessed whether ESWT increases the rate of healing in chronic decubitus ulceration in a double-blind randomized cross-over study. Ulcers were randomized into receiving either the ESWT 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 ESWT, whether treated first with the placebo or the therapy. The authors concluded that ESWT has a potential part to play in the treatment of chronic skin ulceration. This study is limited by a small study population.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

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. Refer to 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 May 31, 2023)

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Policy History/Revision Information

Date	Summary of Changes
10/01/2023	Supporting Information <ul style="list-style-type: none">Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current informationArchived previous policy version CS041KY.08

Instructions for Use

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

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