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

Policy Number: CSNCT0269.03
Effective Date: February 1, 2022

Instructions for Use

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Related Policy
Lithotripsy for Salivary Stones (for North Carolina Only)

Application

This Medical Policy only applies to the state of North Carolina.

Coverage Rationale

Extracorporeal shock wave therapy (ESWT), whether low energy, high energy, or radial wave, is unproven and not medically necessary for any 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 federal, state, or contractual requirements 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

CPT Code	Description
0102T	Extracorporeal shock wave performed by a physician, requiring anesthesia other than local, and involving 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

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 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 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 randomized controlled trials. 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 (HTA), 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 Clinical Excellence (NICE, IPG571) concluded that although the evidence on extracorporeal shock wave 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 randomized controlled trials (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.

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 (SAIS), and medial (MEP) and lateral (LEP) 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 shock waves were nevertheless suggested in prevision of surgical treatment. The authors however reported a moderate overall risk of bias that could have influenced their analysis.

Surace et al. (2020) reviewed 32 RCTs and controlled clinical trials (CCTs) involving 2,281 participants with rotator cuff disease with or without calcific deposits. The primary comparison was shock wave therapy compared to placebo with a three-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.

Bannuru et al. (2014) conducted a systematic review (n = 28 RCTs/1,307 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/mm^2) with low-energy ESWT (< 0.09 mJ/mm^2) 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 RCTs 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; six-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 e 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 (RC) tendinosis. The reviewers found that only high-ESWT is effective for treating calcific RC tendinosis. No evidence was found for the effectiveness of ESWT to treat non-calcific RC 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.

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 [IPG21] 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. Four studies evaluating the efficacy of the procedure all showed an increase in function and a reduction of pain, but the effect of the dose of energy used on efficacy outcomes is unclear. The Specialist Advisors considered that the efficacy of ESWT is uncertain, particularly in relation to the dose of energy used. There are no registries, and no trials are currently being performed. (NICE, 2003; 2012c)

Clinical Practice Guidelines

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 shock wave 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, shock wave therapy (SWT) using high energy is effective in reducing pain in calcific tendinitis of the shoulder. Evidence suggests that 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 shock waves 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)

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

Evidence in the form of randomized controlled trials (RCT) regarding the efficacy of ESWT for plantar fasciitis is conflicting and inconsistent.

A 2021 Hayes health technology assessment (HTA) reviewed the evidence from ten RCTs for the efficacy of Radial ESWT for chronic plantar fasciitis. The analysis demonstrated a moderate-size body of low-quality evidence with conflicting results. Some evidence showed radial ESWT may decrease patient-reported pain and increase functional outcomes in the short term. Several variations in ESWT treatment protocols were used across studies and many studies did not fully report the treatment parameters used. The body of evidence also included methodological weaknesses such as small sample size, lack of long-term follow-up, high loss to follow-up and confounding from secondary treatments.

Another Hayes HTA (2021) reviewed evidence of Focused ESWT for chronic plantar fasciitis from 17 RCTs with moderate-quality evidence that ESWT may decrease patient-reported pain and increase functional outcomes in the short term; however, the results are conflicting. The evidence shows focused ESWT appears to be relatively safe with transient complications. Due to limitations in current published studies, including conflicting results, lack of blinding, confounding by secondary treatments, and high loss to follow-up, additional studies with stronger methodologies, such as better controlled, blinded, with long-term follow-up are needed to demonstrate safety and effectiveness are needed.

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 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 = nine 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.

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 four-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 six 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 limitation 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 seven 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)

Gerdesmeyer et al. (2008) conducted a multi-center, randomized controlled trial of 245 patients comparing radial extracorporeal shock wave therapy (which works on the superficial skin layers) and placebo in the treatment of chronic plantar fasciitis. All patients underwent three 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.

While studies of high energy (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 low energy (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 three 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.

A 2009 guidance statement from the National Institute for Health and Clinical Excellence (NICE) [IPG311] states that the current evidence on the efficacy of ESWT for refractory plantar fasciitis 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 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.

Clinical Practice Guidelines

American College of Foot and Ankle Surgeons (ACFAS)

In 2017 the American College of Foot and Ankle Surgeons released a consensus statement for the diagnosis and treatment of adult acquired infracalcaneal heel pain. This document includes the statement, "Extracorporeal shock wave therapy (ESWT) is safe and effective in the treatment of plantar fasciitis." A general observation across all studies was that approximately 70% of patients with chronic or subacute plantar fasciitis who underwent ESWT had experienced meaningful improvement in their heel pain at 12 weeks. ESWT, however, does not appear to be an effective first-line option for patients with acute plantar fasciitis.

This consensus does not take into account the issues raised above regarding conflicting findings and potential bias in study results from questionable or lack of blinding, use of subjective and self-reported data, and the other methodological issues.

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 shock wave 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."

A 2009 guidance statement from the National Institute for Health and Clinical Excellence (NICE) [IPG311] states that the current evidence on the efficacy of ESWT for refractory plantar fasciitis 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 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.

Delayed or Nonunion Fractures

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

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 2,027 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 = 1,782) 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 192 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 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 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 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)

Evidence in the form of randomized controlled trials (RCT) regarding the efficacy of ESWT for lateral epicondylitis is conflicting and inconsistent.

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 lateral epicondylitis. The meta-analysis included 13 published RCTs that included 1,035 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 lateral epicondylitis 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 1,104 patients were included in the meta-analysis with 10 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 lateral epicondylitis.

Aydın and Atiç (2018) performed a prospective RCT 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.

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 ≥ 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 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 one and three months 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 one and three months 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 three months after treatment when compared with sham rESWT.

A National Institute for Health and Clinical 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, 2009d; 2012d)

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 lateral epicondylitis (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 six-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.

Clinical Practice Guidelines

American Academy of Orthopaedic Surgeons (AAOS)

Within their educational document on Tennis Elbow, the AAOS states that ESWT creates "'microtrauma' that promotes the body's natural healing processes. Shock wave therapy is considered experimental by many doctors, but some sources show it can be effective." The AAOS does not endorse ESWT in their OrthoInfo educational service on Tennis Elbow (Lateral Epicondylitis). (2015)

Refractory Greater Trochanteric Pain Syndrome (GTPS)

The ECRI Institute published an Executive Summary on the use of ESWT for chronic lateral hip pain / greater trochanteric 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 participates were divided into two groups, both of which were treated with three weekly sessions of focused extracorporeal shock wave treatment (F-ESWT) with the test group (n = 53) receiving an energy flux density (EFD) of 0.20 mJ/mm^2 and the control group (n = 50) receiving the lowest EFD of the device (0.01 mJ/mm^2) 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 randomized clinical trials 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 EWST as an effective intervention and should be considered for GTPS when other nonoperative treatments have failed.

A National Institute for Health and Clinical 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; updated 2012)

Tenosynovitis of the Foot or Ankle

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

Tibialis Tendonitis

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

Wounds

ESWT 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 six 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 10 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 three 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 noted 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 research 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 extracorporeal shock wave therapy 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 (six with incomplete data or lost to follow-up) with acute second-degree burns were randomly to receive standard therapy (burn wound debridement/topical antiseptic therapy) with (n = 22) or without (n = 22) defocused ESWT applied once to the study burn, after debridement. Randomization sequence was computer-generated, and patients were blinded to treatment allocation. Mean time to complete (≥ 95%) epithelialization (CE) for patients that did and did not undergo ESWT was 9.6 ± 1.7 and 12.5 ± 2.2 days, respectively. The authors concluded that the application of a single defocused shock wave treatment to the superficial second-degree burn wound after debridement/topical antiseptic therapy significantly accelerated epithelialization. However, they also indicated that this finding warrants confirmation in a larger phase III trial.

Wang et al. (2011) investigated the molecular changes of ESWT and 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 shock wave 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 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 six to eight 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.

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 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 June 3, 2021)

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Policy History/Revision Information

Date	Summary of Changes
02/01/2022	**Applicable Codes** • Updated list of applicable CPT codes to reflect annual edits; revised description for 0101T, 0102T, 0512T, and 0513T **Supporting Information** • Archived previous policy version CSNCT0269.02

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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