Extracorporeal Shock-Wave Therapy for Musculoskeletal Indications and Soft Tissue Injuries

Number: 0649

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers extracorporeal shock-wave therapy (ESWT) medically necessary for calcific tendinopathy of the shoulder of at least 6 months’ duration with calcium deposit of 1 cm or greater, and who have failed to respond to appropriate conservative therapies (e.g., rest, ice application, and medications).

Aetna considers extracorporeal shock-wave therapy (ESWT), extracorporeal pulse activation therapy (EPAT) (also known as extracorporeal acoustic wave therapy) experimental and investigational for the following indications (not an all-inclusive list) because there is insufficient evidence of effectiveness of ESWT for these indications in the medical literature:

- Achilles tendonitis (tendinopathy)

Policy History

Last Review 07/28/2016
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Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes
Angina pectoris
Breast cancer-related lymphedema
Cellulite
Chronic pelvic pain
Delayed unions
Erectile dysfunction
Heterotopic ossification
Hypertensive nephropathy
Lateral epicondylitis (tennis elbow)
Low back pain
Lower limb ulceration
Medial epicondylitis (golfers elbow)
Non-unions of fractures
Osteonecrosis of the femoral head
Patellar tendinopathy
Peyronie's disease
Rotator cuff tendonitis (shoulder pain)
Spasticity following brain injury/stroke
Spinal cord injury
Stress fractures
Subacromial impingement syndrome/subacromial shoulder pain
Wound healing (including burn wounds)
Other musculoskeletal indications (e.g., calcaneal spur, hammer toe, tenosynovitis of the foot or ankle, and tibialis tendinitis).

See also CPB 0235 - Plantar Fasciitis Treatments (../200_299/0235.html).

Background
Extracorporeal shock wave therapy (ESWT) is a nonsurgical treatment that involves the delivery of shock waves to musculoskeletal areas of the body (commonly the epicondyle, shoulder or heel) with the goal of reducing pain and promoting healing of the affected soft tissue. Shock waves are theorized to reduce inflammation, break up scar tissue and stimulate tissue healing. ESWT is performed on an outpatient basis and may utilize local anesthesia to numb the area targeted for
treatment. ESWT is intended as a noninvasive alternative to surgical treatment in selected patients who have failed conventional medical therapy.

Extracorporeal pulse activation therapy or radial wave therapy is another type of ESWT that uses waves of pressure to transform kinetic energy into radially expanding shock waves. It is purported to be an alternative to focused ESWT and can address larger treatment areas.

Lateral elbow pain (tennis elbow, lateral epicondylitis, rowing elbow) is one of the most commonly encountered repetitive motion injuries; the prevalence of lateral elbow pain in the population has been estimated to be 1 to 3%. Symptoms often persist for 18 months to 2 years and a small proportion of patients eventually undergo surgery.

This overuse syndrome is caused by continued stress on the grasping muscles (extensor carpi radialis brevis and longus) and supination muscles (supinator longus and brevis) of the forearm, which originate on the lateral epicondyle of the elbow.

Conservative treatment involves rest, ice, stretching, strengthening, and lower intensity to allow for maladaptive change. Any activity that hurts on extending or pronating the wrist should be avoided. With healing, exercises to strengthen the wrist extensors can be started. Generally, exercises to strengthen the wrist flexor pronators are also recommended.

The mechanism of action of extracorporeal shock wave therapy (ESWT) in the treatment of lateral elbow pain is not well understood. Techniques for using extracorporeal shock wave therapy for musculoskeletal problems have not yet been standardized and the precise dosages and the optimal frequency of application have not been studied extensively. There is still no consensus on when to differentiate between low- and high-energy shock wave applications. Other outstanding issues include 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 to treatment to reduce painful reactions.

A systematic review of ESWT for lateral epicondylitis has been published by Buchbinder et al (2005). The investigators identified 9 randomized controlled clinical trials trials of ESWT versus placebo for lateral epicondylitis. Five of the studies showed that pain, function and grip strength was the same or slightly more improved with shock wave therapy than with placebo. Four studies demonstrated more improvement with shock wave therapy than placebo therapy. When Buchbinder et al (2005) pooled the data from the 9 trials, they found no statistically significant benefit of ESWT for lateral epicondylitis. The investigators concluded that "[b]ased upon systematic review of nine placebo‐controlled trials involving 1006 participants, there is 'Platinum' level evidence that shock wave therapy provides little or no benefit in terms of pain and function in lateral elbow pain."

In a randomized controlled study (n = 60), Chung and Wiley (2004) concluded that despite improvement in pain scores and pain-free maximum grip strength within groups, there does not appear to be a meaningful difference between treating lateral epicondylitis with ESWT combined with forearm-stretching program and treating with forearm-stretching program alone, with respect to resolving pain within an 8-week period of commencing treatment. Stasinopoulos and Johnson (2005) stated that more research with well-designed randomized control studies is needed to establish the absolute and relative effectiveness of ESWT for tennis elbow. Furthermore, in a systematic review and meta-analysis of clinical trials on physical interventions for lateral epicondylalgia, Bisset et al (2005) stated that ESWT is not beneficial in the treatment of tennis elbow.

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

Medial epicondylitis (golfers elbow) is an overuse injury affecting the flexor-pronator muscle origin at the anterior medial epicondyle of the humerus. Medial epicondylitis is similar to the more common lateral epicondylitis in many respects. Both conditions are overuse tendinopathies that can be associated with racquet sports. Other activities with which medial epicondylitis is associated include golfing, throwing sports, and racquet sports. This condition also has been reported in bowlers, archers, and weightlifters. Pain worsens with wrist flexion and pronation activities. Patients may report discomfort even when simply shaking hands with someone. History of an acute injury may be reported (e.g., taking a divot in golf, throwing a pitch in baseball, a hard serve in tennis). Up to 50% of patients with medial epicondylitis complain of occasional or constant numbness and/or tingling sensation that radiates into their fourth and fifth fingers, suggesting involvement of the ulnar nerve.

An early study of ESWT for medial epicondylitis reported disappointing results (Krischek et al, 2001). This is confirmed by two randomized controlled studies. Haake and associates (2002) concluded that ESWT was ineffective in the treatment of lateral epicondylitis (n = 272). The previously reported success of this therapy appears to be attributable to inappropriate study designs.

Melikyan et al (2003) reported on the results of a double-blind randomized controlled clinical study of ESWT in 74 patients with epicondylitis. The investigators reported no significant differences between treatment and placebo groups in improvements in pain, function or disability. The investigators concluded that "[o]ur study showed no evidence that extracorporeal shock-wave therapy for tennis elbow is better than placebo." A systematic evidence review concluded that the effectiveness of ESWT for tennis elbow is "unknown"
An assessment of ESWT for refractory tennis elbow by the National Institute for Clinical Excellence (NICE, 2009) concluded that, although the evidence on extracorporeal shockwave therapy for refractory tennis elbow raises no major safety concerns, the evidence on its efficacy is inconsistent. "Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research."

The Canadian Agency for Drugs and Technologies in Health (CADTH)'s report on ESWT for chronic lateral epicondylitis (Ho, 2007a) stated that "the lack of convincing evidence regarding its effectiveness does not support the use of ESWT for chronic lateral epicondylitis." The CADTH's report on ESWT for chronic rotator cuff tendonitis (Ho, 2007b) stated that "the evidence reviewed for this bulletin supports the use of high-energy ESWT for chronic calcific rotator cuff tendonitis, but not for non-calcific rotator cuff tendonitis. High-quality randomized controlled trials (RCTs) with larger sample sizes are needed to provide stronger evidence."

Extracorporeal shock wave therapy has also been studied in other musculoskeletal applications, including Achilles tendonitis and shoulder tendonitis. 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. Guidance from the National Institute for Health and Clinical Excellence (NICE, 2009) 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. "Therefore, ESWT for refractory Achilles tendinopathy should only be used with special arrangements for clinical governance, consent and audit or research."

Extracorporeal shock wave therapy has also been used for the
treatment of shoulder pain (calcific tendonitis of the shoulder). In a review on ESWT for the treatment of calcific and non-calcific tendonitis of the rotator cuff, Harniman et al (2004) found that common problem associated with this research area were sample size, randomization, blinding, treatment provider bias, and outcome measures. The investigators found moderate evidence that high-energy ESWT is effective in treating chronic calcific rotator cuff tendonitis when the shock waves are focused at the calcified deposit. Additionally, the investigators found moderate evidence that low-energy ESWT is not effective for treating chronic non-calcific rotator cuff tendonitis, although this conclusion is based on only one high-quality study, which was underpowered. These investigators concluded that high-quality randomized, controlled trials with larger sample sizes, better randomization and blinding, and better outcome measures are needed to ascertain the effectiveness of ESWT for calcific and non-calcific tendonitis of the rotator cuff.

An assessment of extracorporeal shock wave therapy conducted by the Washington State Department of Labor and Industries (2003) concluded that "the evidence establishing the effectiveness [of ESWT] for musculoskeletal conditions remains inconclusive". In a review on plantar fasciitis, Buchbinder (2004) stated that "ESWT has been proposed as an alternative approach on the grounds that it may stimulate healing of soft tissue and inhibit pain receptors. However, the available data do not provide substantive support for its use".

An assessment prepared for the Ohio Bureau of Workers' Compensation (2005) concluded that "[s]tudies have not demonstrated consistent results or efficacy in the treatment of plantar fasciitis, epicondylitis, and noncalcific tendonitis of the shoulder. ESWT is considered unproven and investigational for these services." The assessment noted that although "[u]se of ESWT in the treatment of x-ray confirmed calcific tendonitis of the shoulder shows preliminary good results", that "[r]eplication of the results with additional studies would be beneficial prior to acceptance."
In a single-blind, randomized, controlled trial, Engebretsen et al (2011) evaluated the results of radial ESWT (rESWT) and supervised exercises (SE) provided to patients with subacromial shoulder pain after 1 year. A total of 104 patients with subacromial shoulder pain lasting at least 3 months were included in this study. Patients were randomly assigned to either an rESWT group (n = 52) or an SE group (n = 52). The rESWT intervention consisted of 1 session weekly for 4 to 6 weeks. The SE intervention consisted of 2 45-min sessions per week for up to 12 weeks. The primary outcome measure was the Shoulder Pain and Disability Index. Secondary outcome measures were questions regarding pain and function and work status. After 1 year, an intention-to-treat analysis showed no significant differences between the 2 groups for the primary outcome measure (-7.6 points, 95 % confidence interval [CI]: -16.6 to 0.5) and pain, function, and medication use. Twenty-nine participants (60 %) in the SE group versus 24 participants (52 %) in the rESWT group were categorized as clinically improved. Thirty-eight participants in the SE group were at work compared with 30 participants in the rESWT group (odds ratio = 1.1, 95 % CI: 1.0 to 1.2). Fewer patients in the SE group had received additional treatments between 18 weeks and 1 year. The authors concluded that no significant difference was found between the SE and rESWT groups at the 1-year follow-up. More participants in the SE group had returned to work.

In the last decade, ESWT has become a common tool for the treatment of non-unions. Rompe et al (2001) reported that although high-energy shock wave therapy seemed to be an effective non-invasive tool for stimulation of bone healing in properly selected patients with a diaphyseal or metaphyseal nonunion of the femur or tibia, additional controlled studies are mandatory. In a review on the use of ESWT in the treatment of non-unions, Birnbaum et al (2002) stated that presently ESWT is not yet a standard therapeutic technique in orthopedics. These investigators concluded that the primary aim of further research should be the evaluation of adequate energy density levels and impulse rates for various indications in accordance
with evidence-based medicine. Well-designed studies with long-term follow-ups are needed before ESWT can be compared with established methods.

Biedermann et al (2003) stated that nonunion remains a major complication after skeletal trauma. However, to date, no prospective, randomized trial has been conducted to show the efficacy of this form of treatment. The authors concluded that no evidence supports the treatment of pseudarthroses with ESWT. A randomized, prospective, clinical trial with a control group has to be performed before a final decision can be made regarding this indication for ESWT. An assessment prepared for the Ohio Bureau of Workers’ Compensation (2004) concluded that additional studies of ESWT in non-unions are needed.

Available brands of ESWT devices include the OssaTron (HealthTronics, Marietta, GA), the Dornier Epos Ultra (Dornier Medical Systems, Kennesaw, GA), and the Sonocur (Siemens Medical Solutions Inc., Iselin, NJ).

Seil et al (2006) stated that shock waves, as applied in urology and gastroenterology, were introduced in the middle of the last decade in Germany to treat different pathologies of the musculoskeletal system, including epicondylitis of the elbow, plantar fasciitis, and calcifying and non-calcifying tendinitis of the rotator cuff. With the non-invasive nature of these waves and their seemingly low complication rate, ESWT seemed a promising alternative to the established conservative and surgical options in the treatment of patients with chronically painful conditions. However, the apparent advantages of the method led to a rapid diffusion and even inflationary use of ESWT. The authors noted that prospective, randomized studies on the mechanisms and effects of shock waves on musculoskeletal tissues are urgently needed to define more accurate indications and optimize therapeutic outcome.

In a double-blind, randomized, placebo-controlled study, Staples et al (2008) examined if ultrasound-guided ESWT reduced pain and improved function in patients with lateral
epicondylitis (tennis elbow) in the short-term and intermediate-term. A total of 68 patients from community-based referring doctors were randomized to receive 3 ESWT treatments or 3 treatments at a sub-therapeutic dose given at weekly intervals. Seven outcome measures relating to pain and function were collected at follow-up evaluations at 6 weeks, 3 months, and 6 months after completion of the treatment. The mean changes in outcome variables from baseline to 6 weeks, 3 months, and 6 months were compared for the 2 groups. The groups did not differ on demographical 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 these findings provided little evidence to support the use of ESWT for the treatment of lateral epicondylitis and is in keeping with recent systematic reviews of ESWT for lateral epicondylitis that have drawn similar conclusions.

In a review on the treatment of epicondylitis, Schleicher et al (2010) noted that the choice of different treatments is hard to overlook and there are only a few good clinical trials that supported one treatment option by means of evidence based medicine. During the acute phase, topical non-steroidal anti-inflammatory drugs, steroid injections, ultrasound and acupuncture are helpful. There is no consensus about the effectiveness of physiotherapy, orthoses, laser, electrotherapy or botulinum toxin injections. During the chronic phase, none of the different treatment modalities is effective according to criteria of evidence-based medicine. By now, it has not been proven whether patients profit during that time of physiotherapy, orthoses, ESWT or an operation.

Hearnden and colleagues (2009) stated that ESWT has been claimed to be an effective non-invasive treatment for chronic calcific tendonitis of the supra-spinatus tendon. However, many trials have been criticised for not achieving necessary scientific standards. In a prospective, single-blinded,
randomized control trial of 20 patients, these investigators examined the effectiveness of the therapy. Subjectively, 45% of the treated patients were satisfied with the outcome and also had objectively increased their Constant score by 11% at 6 months. The control group experienced no subjective or objective improvement (p < 0.03). This study confirmed that ESWT is effective in treating chronic calcific tendonitis when compared with a placebo group. However, in the authors’ experience it is not as successful as previously claimed, with 50% of the patients failing to achieve a satisfactory outcome and requiring surgical excision. Moreover, patients found the procedure painful, which has not been alluded to previously.

Schaden et al (2007) evaluated the feasibility and safety of ESWT for acute and chronic soft tissue wounds. A total of 208 patients with complicated, non-healing, acute and chronic soft tissue wounds were prospectively enrolled onto this trial. Treatment consisted of debridement, out-patient ESWT [100 to 1000 shocks/cm(2) at 0.1 mJ/mm(2), according to wound size, every 1 to 2 week over a mean of 3 treatments], and moist dressings. Thirty-two (15.4%) patients dropped out of the study following first ESWT and were analyzed on an intent-to-treat basis as incomplete healing. Of 208 patients enrolled, 156 (75%) had 100% wound epithelialization. During mean follow-up period of 44 days, there was no treatment-related toxicity, infection, or deterioration of any ESWT-treated wound. Intent-to-treat multi-variate analysis identified age (p = 0.01), wound size less than or equal to 10 cm(2) (p = 0.01; odds ratio [OR] = 0.36; 95% CI: 0.16 to 0.80), and duration less than or equal to 1 month (p < 0.001; OR = 0.25; 95% CI: 0.11 to 0.55) as independent predictors of complete healing. The authors concluded that the ESWT strategy is feasible and well-tolerated by patients with acute and chronic soft tissue wounds. They noted that ESWT is being evaluated in a phase III trial for acute traumatic wounds.

Alves et al (2009) stated that osteonecrosis is a progressive clinical condition with significant morbidity, which primarily
affects weight-bearing joints and is characterized by the death of the bone, or part of it, because of insufficient circulation. The hip is the most common compromised joint. In osteonecrosis of the femoral head (ONFH), the collapse of the femoral head is a result of mechanically weak bone submitted to a load of weight, and can be associated with incapacitating pain and immobility. Both surgical as well as non-surgical options have been used with differing levels of success, and non-operative treatment modalities such as bisphosphonates, statins, anti-coagulants, and ESWT for early-stage disease have been described, but exact indications have not been established yet. The aim of this study was to make a systematic review of the use of ESWT in the treatment of ONFH. Medline, Lilacs, and Scielo databases were searched using the keywords "shock wave", "osteonecrosis", "avascular necrosis", "aseptic necrosis" and "femoral head". The search period was between 1966 and 2009. Only 5 articles that fulfilled the previously established criteria were obtained. Of these 5 articles, 2 were RCTs, 1 open label study, 1 comparative prospective study, and 1 was a case report. This review demonstrated that there are no controlled and double-blind studies about the efficacy of ESWT in the treatment of ONFH. On the other hand, the published non-controlled studies appear to demonstrate some favorable result, which justifies new research in this area.

Larking and associates (2010) examined if ESWT increases the rate of healing in patients with chronic neurological conditions and chronic decubitus ulceration. Ulcers were randomized into receiving either the ESWT or the placebo for a 4-week period, followed by a 2-week "washout" period followed by a 4-week period of the cross-over treatment/placebo. Main outcome measure was measurement of the area of the ulceration. For each observation the average of 3 measurements were taken. A total of 9 ulcers (in 8 patients) were included in the study: 5 on the buttocks/sacrum/trochanter and 4 on the feet/ankles. All those with static chronic ulcers showed improved healing starting 6 to 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. The findings of this small study need to be validated by well-designed studies.

Zelle and colleagues (2010) provided a concise review of the basic science of ESWT and performed a systematic review of the literature for the use of ESWT in the treatment of fractures and delayed unions/non-unions. Articles in the English or German language were identified for the systematic review by searching PubMed-Medline from 1966 until 2008, Cochrane database of systematic reviews, Cochrane database of abstracts of reviews of effects, Cochrane central register of controlled trials, and relevant meeting abstracts from 2007 to 2008. Moreover, the bibliographies of the identified articles were reviewed. These investigators included clinical outcome studies of ESWT in the treatment of fractures and delayed unions/non-unions. Reports with less than 10 patients were excluded. Non-unions after corrective osteotomies or arthrodeses were excluded. Sample size, level of evidence, definition of delayed union, definition of non-union, time from injury to shock wave treatment, location of fracture, union rate, and complications were extracted from the identified articles. Data of 924 patients undergoing ESWT for delayed union/non-union were extracted from 10 studies. All articles were graded as level 4 studies. The overall union rate was 76 % (95 % CI: 73 % to 79 %). The union rate was significantly higher in hypertrophic non-unions than in atrophic non-unions. The authors concluded that data from level 4 studies suggested that ESWT seems to stimulate the healing process in delayed unions/non-unions. However, they stated that further investigations are needed.

Interventional procedure consultation from the National Institute for Health and Clinical Excellence (NICE, 2011) concluded that evidence of the safety and efficacy of ESWT for greater trochanteric pain syndrome is of limited quality and quantity. The guidance stated that NICE encourages further research into ESWT for refractory greater trochanteric pain syndrome. Research studies should clearly describe patient selection, imaging, and treatment protocols. Outcomes should include functional and quality-of-life scores with at least 1 year
Rompe et al (2009) reported on a comparative study involving 229 subjects with refractory unilateral greater trochanter pain syndrome who were assigned sequentially to a home training program, a single local corticosteroid injection (25 mg prednisolone), or a repetitive low-energy radial shock wave treatment. Subjects underwent outcome assessments at baseline and at 1, 4, and 15 months. Primary outcome measures were degree of recovery, measured on a 6-point Likert scale (subjects with rating completely recovered or much improved were rated as treatment success), and severity of pain over the past week (0 to 10 points) at 4-month follow-up. One month from baseline, results after corticosteroid injection (success rate, 75%; pain rating, 2.2 points) were significantly better than those after home training (7%; 5.9 points) or shock wave therapy (13%; 5.6 points). Regarding treatment success at 4 months, radial shock wave therapy led to significantly better results (68%; 3.1 points) than did home training (41%; 5.2 points) and corticosteroid injection (51%; 4.5 points). Fifteen months from baseline, radial shock wave therapy (74%; 2.4 points) and home training (80%; 2.7 points) were significantly more successful than was corticosteroid injection (48%; 5.3 points). The authors reported that the significant short-term superiority of a single corticosteroid injection over home training and shock wave therapy declined after 1 month. The authors reported that both corticosteroid injection and home training were significantly less successful than was shock wave therapy at 4-month follow-up. Corticosteroid injection was significantly less successful than was home training or shock wave therapy at 15-month follow-up.

In a prospective, randomized, controlled trial, Chitale et al (2010) compared limited ESWT versus sham therapy in men with Peyronie’s disease. A total of 36 men were randomized to 6 sessions of ESWT or sham treatment. Geometrical measurements of penile length and deformity, and the abridged International Index of Erectile Function (IIEF) score and visual analog score (VAS) were recorded and re-evaluated
at 6 months. The patient and assessor were unaware of the treatment type. Standard non-parametric tests were used for the statistical analysis. A full set of outcome data was obtained for 16 patients in the intervention group and 20 in the sham/control group (mean age of 58 and 60 years; mean duration of symptoms of 15 and 33 months, respectively).

There was no significant difference in the mean change between the control and intervention groups on any outcome measure. There were improvements in the mean (S.D.) dorsal and lateral angle, of 5.3 (11.66) degrees and 3.5 (17.38) degrees in the control group, and a deterioration of 0.9 (16.01) degrees and 0.9 (15.56) degrees in the ESWT group. Mean improvements in curved and straight lengths were 0.2 (0.58) and 0.1 (0.8) cm in the control and mean reductions of 1.1 (0.9) and 0.1 (1.49) cm in the ESWT group. The mean changes in the IIEF and VAS scores were 0.1 (3.32) and -0.8 (1.77) for control and 0.56 (2.6) and -1.05 (1.79) for ESWT group. The authors concluded that there were no significant differences in changes of variables in Peyronie’s disease treated with short-term ESWT.

In a systematic review, Seco et al (2011) evaluated the evidence on the efficacy, effectiveness, cost-effectiveness, and safety of ultrasound and shock wave to treat low back pain (LBP). An electronic search was performed in MEDLINE, EMBASE, and the Cochrane Library databases up to July 2009 to identify RCTs comparing vibrotherapy with placebo or with other treatments for LBP. No language restrictions were applied. Additional data were requested from the authors of the original studies. The risk of bias of each study was assessed following the criteria recommended by the Cochrane Back Review Group. A total of 13 studies were identified. The 4 RCTs complying with the inclusion criteria included 252 patients; 2 of the 3 RCTs on ultrasound had a high-risk of bias. For acute patients with LBP and leg pain attributed to disc herniation, ultrasound, traction, and low-power laser obtained similar results. For chronic LBP patients without leg pain, ultrasound was less effective than spinal manipulation, whereas a shock wave device and transcutaneous electrical nerve stimulation led to similar
results. Results from the only study comparing ultrasound versus a sham procedure are unreliable because of the inappropriateness of the sham procedure, low sample size, and lack of adjustment for potential confounders. No study assessed cost-effectiveness; no adverse events were reported. The authors concluded that available evidence does not support the effectiveness of ultrasound or shock wave for treating LBP. They stated that high-quality RCTs are needed to assess their efficacy versus appropriate sham procedures, and their effectiveness and cost-effectiveness versus other procedures shown to be effective for LBP. In the absence of such evidence, the clinical use of these forms of treatment is not justified and should be discouraged.

In a phase II clinical study, Ottomann et al (2012) examined shock wave effects in burn wounds. A pre-defined cohort of 50 patients (6 with incomplete data or lost to follow-up) with acute second-degree burns from a larger study of 100 patients were randomly assigned between December 2006 and December 2007 to receive standard therapy (burn wound debridement/topical anti-septic therapy) with (n = 22) or without (n = 22) defocused ESWT (100 impulses/cm at 0.1 mJ/mm) applied once to the study burn, after debridement. Randomization sequence was computer-generated, and patients were blinded to treatment allocation. The primary endpoint, time to complete burn wound epithelialization, was determined by independent, blinded-observer. A worst case scenario was applied to the missing cases to rule out the impact of withdrawal bias. Patient characteristics across the 2 study groups were balanced (p > 0.05) except for older age (53 +/- 17 versus 38 +/- 13 years, p = 0.002) in the ESWT group. Mean time to complete (greater than or equal to 95 %) epithelialization (CE) for patients that did and did not undergo ESWT was 9.6 +/- 1.7 and 12.5 +/- 2.2 days, respectively (p < 0.0005). When age (continuous variable) and treatment group (binary) were examined in a linear regression model to control the baseline age imbalance, time to CE, age was not significant (p = 0.33) and treatment group retained significance (p < 0.0005). Statistical significance (p = 0.001) was retained when
ESWT cases with missing follow-up were assigned the longest time to CE and when controls with missing follow-up were assigned the shortest time to CE. The authors concluded that in this randomized phase II study, application of a single defocused shock wave treatment to the superficial second-degree burn wound after debridement/topical anti-septic therapy significantly accelerated epithelialization. They stated that this finding warrants confirmation in a larger phase III trial. Drawbacks of this study included absence of burn wound histology, modest sample size, and lack of long-term follow-up.

Vardi and colleagues (2012) examined the clinical and physiological effect of low-intensity ESWT on men with organic erectile dysfunction who are phosphodiesterase type 5 inhibitor responders. After a 1-month phosphodiesterase type 5 inhibitor wash-out period, 67 men were randomized in a 2:1 ratio to receive 12 sessions of low-intensity ESWT or sham therapy. Erectile function and penile hemodynamics were assessed before the first treatment (visit 1) and 1 month after the final treatment (follow-up 1) using validated sexual function questionnaires and veno-occlusive strain gauge plethysmography. Clinically, these investigators found a significantly greater increase in the International Index of Erectile Function-Erectile Function domain score from visit 1 to follow-up 1 in the treated group than in the sham-treated group (mean +/- SEM 6.7 +/- 0.9 versus 3.0 +/- 1.4, p = 0.0322). There were 19 men in the treated group who were initially unable to achieve erections hard enough for penetration (Erection Hardness Score 2 or less) who were able to achieve erections sufficiently firm for penetration (Erection Hardness Score 3 or greater) after low-intensity ESWT, compared to none in the sham group. Physiologically penile hemodynamics significantly improved in the treated group but not in the sham group (maximal post-ischemic penile blood flow 8.2 versus 0.1 ml/min/dL, p < 0.0001). None of the men experienced discomfort or reported any adverse effects from the treatment. The authors concluded that this is the first randomized, double-blind, sham controlled study to their knowledge that shows that low-intensity ESWT has a positive short-term clinical and
physiological effect on the erectile function of men who respond to oral phosphodiesterase type 5 inhibitor therapy. The feasibility and tolerability of this treatment, coupled with its potential rehabilitative characteristics, make it an attractive new therapeutic option for men with erectile dysfunction. They stated that additional studies with long-term follow-up are needed to assess the effectiveness of this new therapy and confirm these findings.

Kearney and Costa (2010) reviewed evidence for interventions specific to insertional Achilles tendinopathy. Medline and the Cochrane library were searched using a pre-defined search strategy. All study designs were included except case studies, narrative reviews, technical notes and letters/personal opinion. The results were evaluated independently by 2 reviewers and assessed against the inclusion/exclusion criteria. All included articles were assessed for methodological quality and study characteristics were extracted into a table. A total of 118 articles were identified through the search strategy, of which 11 met the eligibility criteria. Six studies evaluated operative techniques following failed conservative management and 5 evaluated conservative interventions only. The overall level of evidence was limited to case-series evaluations and 1 RCT. The authors concluded that there is a consensus that conservative methods should be used before operative interventions. Current evidence for conservative treatment favors eccentric loading and shock-wave therapy, although there is limited evidence by which to judge their effectiveness. Evaluation of operative interventions has been mostly retrospective and remains inconclusive.

An UpToDate review on “Achilles tendinopathy and tendon rupture” (Ham and Maughan, 2013) states that “Further study is needed to determine the role of shock wave therapy and topical nitrates. Surgical treatment for chronic tendinopathy may be considered in refractory cases, but has not been well studied”.

Gaida and Cook (2011) stated that patellar tendinopathy is a
painful knee injury due to overuse common among jumping athletes. Because rest from sport is neither a feasible nor an effective treatment for patellar tendinopathy in elite athletes, active treatment options are needed. Treatment may be conservative, injection-based, or surgical. This review synthesized findings from 32 studies of varying quality published between 2001 and 2011. Painful eccentric squats using a 25°-decline board is supported as a first-line treatment. Extracorporeal shock wave therapy is no more effective than placebo. Sclerosing injections seem to be effective, but the evidence is not definitive. Shaving of abnormal tissue via arthroscopic surgery with real-time ultrasound guidance is superior to sclerosing injections. Steroid injections are inferior to exercise interventions and are not recommended. Injections of autologous blood, platelet-rich plasma, and hyper-osmolar dextrose are unproven and experimental.

Larsson et al (2012) systematically reviewed, summarized and compared treatments for patellar tendinopathy from published RCTs. Database searches were performed for prospective RCTs comparing treatment methods for patellar tendinopathy. The 13 articles considered relevant were scrutinized according to quality assessment guidelines and levels of evidence. Strong evidence was found for the use of eccentric training to treat patellar tendinopathy. Moderate evidence was found for conservative treatment (heavy slow resistance training) as an alternative to eccentric training. Moderate evidence suggested that low-intensity pulsed ultrasound treatment did not influence treatment outcomes. Limited evidence was found for surgery, sclerosing injections, and shockwave therapy. The authors concluded that physical training, and particularly eccentric training, appears to be the treatment of choice for patients suffering from patellar tendinopathy. However, type of exercise, frequency, load, and dosage must also be analyzed. Other treatment methods, such as surgical treatment, sclerosing injections, and shockwave therapy, must be investigated further before recommendations can be made regarding their use. Ultrasound can likely be excluded as a treatment for patellar tendinopathy. There is a persistent lack
of well-designed studies with sufficiently long-term follow-up and number of patients to draw strong conclusions regarding therapy.

Also, an UpToDate review on “Plantar fasciitis and other causes of heel pain” (Buchbinder, 2013) states that “In patients without sufficient improvement from initial measures, more costly therapies can be considered, although these remain unproven .... molded shoe inserts (orthotics), night splints, immobilization with a cast, extracorporeal shock wave therapy .... The effectiveness of extracorporeal shock wave therapy for plantar fasciitis has been more extensively studied than any other single treatment modality. A number of randomized trials have compared shock wave therapy with either placebo or sub-therapeutic doses of shock waves. These trials have been of variable methodological quality and have reported conflicting results. A systematic review published in 2005 included 11 trials and performed a pooled analysis of data from six trials involving 897 patients. The authors concluded that there was no clinically important benefit of shock wave therapy despite a small statistically significant benefit in morning pain of less than 0.5 cm on a 10 cm visual analogue scale. No statistically significant benefit was observed in a sensitivity analysis that only included high-quality trials. A subsequent trial of a pneumatic low-energy extracorporeal shock wave device also reported that outcomes from shock wave treatment were no better than sham therapy in a trial of 25 participants. There is ongoing clinical uncertainty about the effectiveness of shock wave therapy; opinions are highly polarized, fueled by the lack of convergence of findings from randomized evaluations. Explanations that have been put forward to explain the differing results include variation in methodological quality, the different types of equipment that have been used to generate the shock waves, different delivery methods, and different doses”.

More recently, a variation of ESWT, also known as extracorporeal pulse activation therapy (EPAT) and extracorporeal acoustic wave therapy, has been proposed for
orthopedic conditions and soft tissue inflammation. This low-energy, pulse-activated shockwave technology is supposedly based on a unique set of pressure waves that stimulate the metabolism, enhance blood circulation and accelerate the healing process. Damaged tissue gradually regenerates and eventually heals.

Saxena and colleagues (2011) evaluated the effectiveness of 3 weekly EPAT in patients with Achilles tendinopathy, as quantified by the Roles and Maudsley score. A total of 74 tendons in 60 patients were assessed at baseline and at least 1 year post-treatment, including 32 (43.24%) para-tendinoses, 23 (31.08%) proximal tendinoses, and 19 (25.68%) insertional tendinoses. The mean age of the participants was 48.6 ± 12.94 years, and patients with para-tendinosis (41.44 ± 14.01 years) were statistically significantly younger than those with proximal (53 ± 8.9 years) and insertional (54.26 ± 9.74 years) tendinopathy, and these differences were statistically significant (p = 0.0012 and p = 0.0063, respectively). Overall, 58 (78.38%) tendons improved by at least 1 year post-treatment, including 75% in the para-tendinosis, 78.26% in the proximal tendinosis, and 84.21% in the insertional tendinosis groups, and no adverse effects were observed. The Roles and Maudsley score improved from 3.22 ± 0.55 to 1.84 ± 1.05 (p < 0.0001) in the para-tendinosis group, 3.39 ± 0.5 to 1.57 ± 0.66 (p < 0.0001) in the proximal tendinopathy group, and 3.32 ± 0.58 to 1.47 ± 0.7 (p = 0.0001) in the insertional tendinopathy group. Based on these results, the authors believed that EPAT serves as a safe, viable, and effective option for the treatment of Achilles tendinopathy. While these findings were promising, the lack of randomization, control group, and blinding, limited the utility of these data. Well-designed studies are needed to ascertain the safety and effectiveness of EPAT.

The Work Loss Data Institute’s clinical guidelines on “Ankle & foot (acute & chronic)” (2013) and “Elbow (acute & chronic)” (2013) listed ESWT as one of the interventions/procedures that were considered but are not currently recommended. Furthermore, the Work Loss Data Institute’s clinical guidelines
on “Burns” (2013) and “Knee & leg (acute & chronic)” listed ESWT as one of the interventions/procedures that are under study and are not specifically recommended.

Calcific tendonitis is a condition that causes the formation of a small, usually about 1- to 2-cm size, calcium deposit within the tendons of the rotator-cuff. These calcium deposits are usually found in patients at least 30 to 40 years old, and are more common in diabetics. Treatment of calcific tendonitis usually entails rest, ice application, and medications.  

[http://orthopedics.about.com/od/rotatorcuff/a/calcific.htm](http://orthopedics.about.com/od/rotatorcuff/a/calcific.htm).

In a RCT, Pan and colleagues (2003) evaluated the therapeutic effect of ESWT in shoulders with chronic calcific tendinitis, compared the functional outcomes of ESWT and transcutaneous electric nerve stimulation (TENS) therapy, and investigated which types of calcium deposit effectively respond to ESWT. A total of 60 patients with continuous shoulder pain for 6 months or more and with radiographically and sonographically verified calcific tendinitis were included in this study. Patients were randomly allocated to receive ESWT (33 shoulders) or TENS treatment (30 shoulders). Extracorporeal shock-wave therapy was performed with 2,000 shock waves at 2Hz and energy level between 0.26 and 0.32 mJ/mm(2) per session. Treatment was given in 2 sessions, 14 days apart. Transcutaneous electric nerve stimulation was given 3 times a week for 4 weeks. Main outcome measures included mean Constant score, VAS, manual muscle test, and changes of sonographic size and shape of calcium deposits were calculated for 4 time-points: at baseline, 2 weeks, 4 weeks, 12 weeks post-therapy. In both groups, Constant score and VAS improved significantly at 2-, 4-, and 12-week follow-ups (p < 0.05), and the size of calcium deposits decreased significantly at the 4- and 12-week follow-ups. Moreover, the arc-shaped calcific plaques of the rotator-cuff were markedly ameliorated with ESWT. The authors concluded that ESWT is more effective in the treatment of chronic calcific tendinitis of the shoulder than is TENS therapy, especially for arc-type calcific plaque.
Dingemanse et al (2014) presented an evidence-based overview of the effectiveness of electrophysical modality treatments for both medial and lateral epicondylitis (LE). Searches in PubMed, EMBASE, CINAHL and Pedro were performed to identify relevant RCTs and systematic reviews. Two reviewers independently extracted data and assessed the methodological quality. A best-evidence synthesis was used to summarize the results. A total of 2 reviews and 20 RCTs were included, all of which concerned LE. Different electrophysical regimens were evaluated: ultrasound, laser, electrotherapy, ESWT, TENS and pulsed electromagnetic field therapy. Moderate evidence was found for the effectiveness of ultrasound versus placebo on mid-term follow-up. Ultrasound plus friction massage showed moderate evidence of effectiveness versus laser therapy on short-term follow-up. On the contrary, moderate evidence was found in favor of laser therapy over plyometric exercises on short-term follow-up. For all other modalities only limited/conflicting evidence for effectiveness or evidence of no difference in effect was found. The authors concluded that potential effectiveness of ultrasound and laser for the management of LE was found. Moreover, they stated that to draw more definite conclusions high-quality RCTs examining different intensities are needed as well as studies focusing on long-term follow-up results.

In a systematic review and meta-analysis, Ioppolo et al (2013) evaluated the effectiveness of shock wave therapy (SWT) for functional improvement and the reduction of pain in patients with calcific tendinitis of the shoulder, and determined the rate of disappearance of calcifications after therapy at 6 months' follow-up. Articles were searched from the Cochrane Library, MEDLINE, Embase, CINAHL, and Ovid database. These researchers included RCTs from 1992 to 2011, and their quality was assessed using the Physiotherapy Evidence Database (PEDro) scale. Studies were evaluated by 2 independent reviewers for their methodologic quality. Disagreements were settled by a 3rd reviewer. Data were then extracted and cross-checked for accuracy. The reviewers were not blinded to the authors of the articles. In 4 of the 6 studies included for review,
the resorption of calcifications was evaluated using meta-analysis because the studies had 2 treatment groups, while the other 2 studies were analyzed descriptively because they had 3 treatment groups. Fixed- and random-effects models were used to meta-analyze total and partial resorption ratios, and I(2) statistics were calculated to assess heterogeneity. The authors found a clinical improvement with a pooled total resorption ratio of 27.19 (95% CI: 7.20 to 102.67) and a pooled partial resorption ratio of 16.22 (95% CI: 3.33 to 79.01). They stated that SWT increases shoulder function, reduces pain, and is effective in dissolving calcifications. These results were maintained over the following 6 months.

In a systematic review, Bannuru et al (2014) evaluated the effectiveness of ESWT in patients with calcific and non-calcific tendinitis of the shoulder. MEDLINE, Cochrane Central Register of Controlled Trials, EMBASE, Web of Science, and Google Scholar were searched up to November 1, 2013. Randomized, controlled trials comparing high-energy versus low-energy ESWT or placebo for treatment of calcific or non-calcific tendinitis of the shoulder were selected for analysis. Outcome measures included pain (VAS score), functional assessment (Constant-Murley score), and resolution of calcifications. Three independent reviewers abstracted data and determined eligibility and quality by consensus. A total of 28 RCTs met the inclusion criteria. Studies were heterogeneous; 20 RCTs compared ESWT energy levels and placebo and consistently showed that high-energy ESWT was significantly better than placebo in decreasing pain and improving function and resorption of calcifications in calcific tendinitis. No significant difference was found between ESWT and placebo in treatment of 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. This therapy may be under-utilized for a condition that can be difficult to manage.

Verstraelen et al (2014) performed a systematic review and meta-analysis of randomized trials to answer 2 clear research
questions: (i) Is there a greater increase in the Constant-Murley score in patients treated with high-energy ESWT compared with those treated with low-energy ESWT by 3 months and by 6 months? and (ii) Is there a greater chance of complete resorption of the calcifications in patients treated with high-energy ESWT compared with those treated with low-energy ESWT by 3 months and by 6 months? Five relevant electronic online databases, Medline (through PubMed), EMBASE (through OVID), Cinahl (through EBSCO), Web of Science, and the Cochrane Central Register of Controlled Trials, were systematically searched. These researchers also cross-checked the reference lists of articles and reviews for possible relevant studies. Eligible for inclusion were all RCTs that compared high-energy ESWT (greater than 0.28 mJ/mm2) with low-energy ESWT (less than 0.08 mJ/mm2). One author examined titles and abstracts of each identified study to assess study eligibility. Two reviewers independently extracted data and assessed the risk of bias and study quality. The primary outcome measure, the Constant-Murley score, was assessed by comparing mean functional outcome scores between the groups. Secondary outcomes were assessed using ORs, when appropriate data were pooled. Based on this process, 5 RCTs (359 participants) were included. All 5 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 3 and 6 months. The 3-month mean difference was 9.88 (95 % CI: 9.04 to 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 3 months. The corresponding OR was 3.40 (95 % CI: 1.35 to 8.58) and \( p = 0.009 \) (6-month data could not be pooled). The authors concluded that when shock wave therapy is chosen, high-energy shock wave therapy is more likely to result in improved Constant-Murley score and resorption of the deposits compared with low-energy therapy.

Furthermore, the Work Loss Data Institute’s clinical guideline on “Shoulder (acute & chronic)” (2013) listed ESWT as one of the interventions/procedures that were considered and
Guidelines on management of rotator cuff syndrome in the workplace (Hopman, et al., 2013) state that over the last decade, several studies indicate the use of extracorporeal shockwave therapy can successfully treat chronic calcific tendonitis. The guidelines explain that EWST produces pressure waves which are believed to induce fragmentation of calcium deposits and stimulate their re-absorption. The low energy form of these waves is believed to relieve pain while high energy waves have been found to increase regional blood flow, produce capillary lesions and growth of new capillaries. The guidelines report that this treatment of calcific tendonitis can be painful, and usually requires local anaesthesia in order for it to be tolerated by the patient. Contraindications for this therapy include pregnancy, cardiac pacemakers or anticoagulant medications.

On the other hand, an UpToDate review on “Rotator cuff tendinopathy” (Simons and Kruse, 2014) lists ESWT as one of the experimental treatments.

In a meta-analysis, Lee and colleagues (2014a) assessed the effects of ESWT on reducing spasticity immediately and 4 weeks after application of ESWT. These investigators searched PubMed, TCL, Embase, and Scopus from their inception dates through June 2013. The key words "muscle hypertonia OR spasticity" were used for spasticity, and the key words "shock wave OR ESWT" were used for ESWT. A total of 5 studies were ultimately included in the meta-analysis. The Modified Ashworth Scale (MAS) grade was significantly improved immediately after ESWT compared with the baseline values (standardized mean difference [SMD], -0.792; 95 % CI: -1.001 to -0.583). The MAS grade at 4 weeks after ESWT was also significantly improved compared with the baseline values (SMD, -0.735; 95 % CI: -0.951 to -0.519). The authors concluded that ESWT has a significant effect on improving spasticity. Moreover, they stated that further standardization of treatment protocols including treatment intervals and intensities needs to be

recommended.
established and long-term follow-up studies are needed.

In chronic spinal cord injury (SCI), the effectiveness of cell engraftment has been known to be low due to its distinct pathology. Alteration of microenvironment was tried using ESW for chronic SCI. In an animal study, Lee and associates (2014b) presented experimental evidence for cell therapy for SCI. A chronic contusive SCI model was made in 36 Sprague-Dawley rats. The rats were allocated into (i) control group (SCI only), (ii) ESW control group (SCI + ESW), (iii) IV group (SCI + intravenous transplantation of mesenchymal stem cells; MSCs), and (iv) ESW + IV group (SCI + MSCs IV transplantation after ESW). Extracorporeal shock waves were applied at the energy determined by preliminary trials. Engraftment of the cells and expressions of growth factors (brain-derived neurotrophic factor, neuronal growth factor) and cytokines (SDF-1, CXCR4, vascular endothelial growth factor [VEGF]) at the epicenter were assessed. The Basso, Beattie, and Bresnahan locomotor scale was used for the clinical assessment. The mean numbers of engrafted cells were higher in the ESW + IV than that in the IV with a statistical significance. The expression of SDF-1 was higher in the ESW groups than that in the control or IV group; CXCR4 was highly expressed in the transplanted groups. The expressions of growth factors in the treated group were higher in the treated group than those in the control group. However, various statistical significances were noted. The improvement of locomotor was higher in the transplanted groups than that in the control and ESW only group. The authors concluded that at a given energy level, ESW presented more engraftment of the transplanted MSCs without any clinical deterioration in a chronic SCI. They stated that based on this promising result and possible explanations, ESW may cause an alteration of the microenvironment for the cell therapy in chronic SCI.

Yamaya et al (2014) examined if low-energy ESWT promotes VEGF expression and neuroprotection and improves locomotor recovery after SCI. A total of 60 adult female Sprague-Dawley rats were randomly divided into 4 groups: (i) sham group (laminectomy only), (ii) sham-SW group (low-energy ESWT
applied after laminectomy), (iii) SCI group (SCI only), and (iv) SCI-SW group (low-energy ESWT applied after SCI). Thoracic spinal cord contusion injury was inflicted using an impactor. Low-energy ESWT was applied to the injured spinal cord 3 times a week for 3 weeks. Locomotor function was evaluated using the Basso, Beattie, and Bresnahan (BBB) Scale (open field locomotor score) at different time points over 42 days after SCI. Hematoxylin and eosin staining was performed to assess neural tissue damage in the spinal cord. Neuronal loss was investigated by immunostaining for NeuN. The mRNA expressions of VEGF and its receptor, Flt-1, in the spinal cord were assessed using real-time polymerase chain reaction. Immunostaining for VEGF was performed to evaluate VEGF protein expression in the spinal cord. In both the sham and sham-SW groups, no animals showed locomotor impairment on BBB scoring. Histological analysis of H & E and NeuN staining in the sham-SW group confirmed that no neural tissue damage was induced by the low-energy ESWT. Importantly, animals in the SCI-SW group demonstrated significantly better locomotor improvement than those in the SCI group at 7, 35, and 42 days after injury (p < 0.05). The number of NeuN-positive cells in the SCI-SW group was significantly higher than that in the SCI group at 42 days after injury (p < 0.05). In addition, mRNA expressions of VEGF and Flt-1 were significantly increased in the SCI-SW group compared with the SCI group at 7 days after injury (p < 0.05). The expression of VEGF protein in the SCI-SW group was significantly higher than that in the SCI group at 7 days (p < 0.01). The authors concluded that the present study showed that low-energy ESWT significantly increased expressions of VEGF and Flt-1 in the spinal cord without any detrimental effect. Furthermore, it significantly reduced neuronal loss in damaged neural tissue and improved locomotor function after SCI. These results suggested that low-energy ESWT enhances the neuroprotective effect of VEGF in reducing secondary injury and leads to better locomotor recovery following SCI. They stated that the findings of this study provided the first evidence that low-energy ESWT can be a safe and promising therapeutic strategy for SCI.
Butterworth et al (2015) stated that ESWT has been reported as an effective treatment for lower limb ulceration. These researchers investigated the effectiveness of ESWT for the treatment of lower limb ulceration. Five electronic databases (Ovid MEDLINE, CINAHL, Web of Knowledge, Scopus and Ovid AMED) and reference lists from relevant studies were searched in December 2013. All study designs, with the exception of case-reports, were eligible for inclusion in this review. Assessment of each study's methodological quality was performed using the Quality Index tool. The effectiveness of studies was measured by calculating effect sizes (Cohen's d) from means and standard deviations. A total of 5 studies, including; 3 RCTs, 1 quasi-experimental study and 1 case-series design met inclusion criteria and were reviewed. Quality assessment scores ranged from 38 to 63 % (mean of 53 %). Improvements in wound healing were identified in these studies following ESWT. The majority of wounds assessed were associated with diabetes and the effectiveness of ESWT as an addition to standard care has only been assessed in 1 RCT. The authors concluded that considering the limited evidence identified, further research is needed to support the use of ESWT in the treatment of lower limb ulceration.

Yu and colleagues (2015) evaluated the effectiveness of passive physical modalities for the management of soft tissue injuries of the shoulder. MEDLINE, EMBASE, CINAHL, PsycINFO, and the Cochrane Central Register of Controlled Trials were searched from January 1, 1990, to April 18, 2013. Randomized controlled trials and cohort and case-control studies were eligible. Random pairs of independent reviewers screened 1,470 of 1,760 retrieved articles after removing 290 duplicates. A total of 22 articles were eligible for critical appraisal. Eligible studies were critically appraised using the Scottish Intercollegiate Guidelines Network criteria. Of those, 11 studies had a low risk of bias. The lead author extracted data from low risk of bias studies and built evidence tables. A second reviewer independently checked the extracted data. The findings of studies with a low risk of bias were synthesized according to principles of best evidence synthesis. Pre-tensioned tape,
ultrasound, and interferential current were found to be non-effective for managing shoulder pain. However, diathermy and corticosteroid injections led to similar outcomes. Low-level laser therapy provided short-term pain reduction for subacromial impingement syndrome. Extracorporeal shock-wave therapy was not effective for subacromial impingement syndrome but provided benefits for persistent shoulder calcific tendinitis. The authors concluded that most passive physical modalities do not benefit patients with subacromial impingement syndrome. However, low-level laser therapy is more effective than placebo or ultrasound for subacromial impingement syndrome. Similarly, ESWT is more effective than sham therapy for persistent shoulder calcific tendinitis.

The American Urological Association’s guideline on “Peyronie's disease” (Nehra et al, 2015) stated that “Clinicians should not use extracorporeal shock wave therapy (ESWT) for the reduction of penile curvature or plaque size”.

Angina Pectoris:

Slikkerveer and associates (2016) noted that there is a continuing search for new treatment options in patients who suffer from refractory angina pectoris to improve quality of life. Several studies have recently demonstrated promising results by stimulating angiogenesis using ESWT in these patients. These researchers quantitatively analyzed the effect of ESWT on myocardial perfusion in patients with refractory angina pectoris. They included 15 patients with New York Heart Association (NYHA) class 3 to 4 of whom 8 patients underwent baseline and follow-up cardiac magnetic resonance imaging (CMRI). All patients received 9 ESWT sessions of their ischemic zone over a period of 3 months. Quantitative analysis of myocardial perfusion using CMRI revealed no significant improvement of myocardial perfusion after treatment (0.80 ± 0.22 versus 0.76 ± 0.31; p = 0.42). However, the total group of 15 patients did experience a significant improvement in NYHA class (p = 0.034) and reduction of nitroglycerin use (p = 0.012).
The authors concluded that although ESWT was associated with an improvement in NYHA class, they did not observe an improvement in myocardial ischemic zone and perfusion with CMRI. They stated that to unravel the exact mechanisms of ESWT, more in-vitro and animal studies as well as larger (placebo-controlled) studies are needed.

**Breast Cancer-Related Lymphedema:**

In a pilot study, Cebicci and co-workers (2016) the clinical effect of ESWT in patients with secondary lymphedema after breast cancer treatment. Women with a diagnosis of lymphedema secondary to breast cancer (n = 11) were treated for 12 sessions of ESWT with 2,500 impulses each. The treatment frequency was 4-Hz in multiple shock mode. The energy flow density during treatment was equal to a working pressure of 2 bar. The primary outcome measure was volumetric measurements; the secondary outcome measures were the short version of the Disabilities of the Arm, Shoulder and Hand Questionnaire (QuickDASH) and the brief version of the World Health Organization Quality of Life (WHOQOL-BREF). Assessments were conducted by the same investigator at baseline, post-treatment, and at 1, 3, and 6 months after treatment for all patients. Significant reduction was found in the amount of lymphedema with ESWT treatment in all patients, and this reduction was maintained for 6 months. A statistically significant reduction was observed in volumetric measurements for the follow-up period (p = 0.001). The mean volume displacement of the affected upper extremity before treatment was 870.45 ± 384.19 ml at 6 months, and after the treatment it was 604.54 ± 381.74 ml. In addition, improvements were observed in the QuickDASH functional assessment tool and in the physical health domain of the WHOQOL-BREF questionnaire (p = 0.002 and p = 0.007, respectively). The authors concluded that ESWT was shown to provide a reduction in the amount of lymphedema in patients with lymphedema secondary to breast cancer. Also, a marked improvement was observed in the functional status and quality of life of study patients. Treatment efficacy was maintained in the long-term. They
stated that as a non-invasive, novel, method, ESWT is a promising treatment modality for the treatment of lymphedema, which is a chronic, progressive, and refractory condition. These preliminary findings need to be validated by well-designed studies.

Cellulite:

In a meta-analysis, Knobloch and Kraemer (2015) examined the effectiveness of ESWT in cellulite. Electronic databases (such as Ovid Medline, Scopus and Ovid) as well as reference lists of the available studies were evaluated in June 2015 by 2 expert examiners. Assessment of each study's methodological quality was performed with the help of the published quality index tool by Downs and Black. This meta-analysis included a total of 11 clinical trials on the effects of ESWT on cellulite with a total of 297 included females. Among the 11 clinical trials, 5 RCTs on ESWT in cellulite with a total number of 123 females have been published so far. Both, focused ESWT as well as radial ESWT (RESWT) devices have been found effective in treating cellulite so far. Typically, 1 or 2 sessions per week and 6 to 8 sessions overall were studied in the published clinical trials. Overall, outcome parameters mainly focused on digital standardized photographs, circumference measurements and specific ultrasound examinations. Reporting quality showed substantial heterogeneity from 22 to 82 points with a mean of 57 points. The authors concluded that this meta-analysis identified 11 published clinical studies on ESWT in cellulite with 5 RCTs among them. There is growing evidence that both, RESWT as well as focused ESWT and the combination of both are able to improve the degree of cellulite. Typically, 6 to 8 treatments once- or twice-weekly have been studied. Moreover, they stated that long-term follow-up data beyond 1 year are lacking as well as details on potential combination therapies in cellulite such as with low level laser therapy, cryolipolysis and others.

Chronic Pelvic Pain:

Fojecki and colleagues (2016) evaluated high-level evidence
studies of ESWT for urological disorders. These investigators included RCTs reporting outcomes of ESWT in urology. Literature search on trials published in English using Embase, Medline and PubMed was carried out. The systematic review was performed according to PRISMA guidelines. They identified 10 trials on 3 urological indications; 2 of 3 trials on Peyronie's disease (PD) involving 238 patients reported improvement in pain; however, no clinical significant changes in penile deviation and plaque size were observed; 4 studies on erectile dysfunction (ED) including 337 participants were included. Using International Index of Erectile Function (IIEF-EF) and erectile hardness scale (EHS) data suggested a significant positive effect of ESWT in phosphodiesterase-5 inhibitor (PDE-5i) responders in 2 of 4 trials and 3 of 4 trials, respectively; 3 studies on chronic pelvic pain (CPP) engaging 200 men reported positive changes in National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI). There was considerable heterogeneity between trials both with regard to treatment techniques and outcome measures, making it difficult to compare results. The authors concluded that ESWT may resolve pain in PD patients, while evidence for reducing curvature and plaques size is poor. Effects of ESWT on IIEF in ED patients are inconsistent; however, data on EHS does imply that the treatment potentially may recover natural erection in PDE-5i responders; ESWT appeared to be able to resolve pain in CPP patients in the short-term. They stated that in all 3 disease entities, long-term outcome data are needed.

Heterotopic Ossification:

Ryu et al (2016) reported the effects of RESWT on heterotopic ossification (HO). Two cases of neurogenic HO in the upper extremity were administered RESWT using the MASTER PLUS MP 2,000 (Storz, Tägerwilen, Switzerland) and ultrasonographic (US) guidance. The ERSWT protocol consisted of 3,000 pulses at a frequency of 12-Hz during each treatment. The intensity level ranged from 2 to 5 bars, and it was administered 5 times a week for 4 weeks, a total of 20 treatments; RESWT improved pain, range of motion, and hand function in 2 patients with
neurogenic HO in the upper extremity. The authors concluded that further studies are needed to support these results and to understand the mechanism and to devise the protocol of RESWT for neurogenic HO.

**Hypertensive Nephropathy:**

Caron et al (2016) examined if ESWT could ameliorate renal repair and favor angiogenesis in L-NAME-induced hypertensive nephropathy in rats; ESWT was started when proteinuria exceeded 1 g/mmol of creatinine and 1 week after L-NAME removal; ESWT consisted of implying 0.09 mJ/mm² (400 shots), 3 times per week. After 4 weeks of SWT, blood pressure, renal function and urinary protein excretion did not differ between treated (LN + SWT) and untreated rats (LN). Histological lesions including glomerulosclerosis and arteriolosclerosis scores, tubular dilatation and interstitial fibrosis were similar in both groups. In addition, peri-tubular capillaries and eNOS, VEGF, VEGF-R, SDF-1 gene expressions did not increase in ESWT-treated compared to untreated animals. No procedural complications or adverse effects were observed in control (C + ESWT) and hypertensive rats (LN + ESWT). The authors concluded that these findings suggested that ESWT did not induce angiogenesis and did not improve renal function and structure, at least in the model of hypertensive nephropathy although the treatment was well-tolerated.

**Spasticity Following Stroke:**

Li and colleagues (2016) noted that recently, studies have reported that ESWT is a safe, non-invasive, alternative treatment for spasticity. However, the effect of ESWT on spasticity cannot be determined, because most studies to-date have enrolled small patient numbers and have lacked placebo-controlled groups and/or long-term follow-up. In addition, whether varying the number of ESWT sessions would affect the duration of the therapeutic effect has not been investigated in a single study. These researchers performed a prospective, randomized, single-blind, placebo-controlled study to examine
the long-term effect of RESWT in patients with post-stroke spasticity and surveyed the outcome of functional activity. A total of 60 patients were randomized into 3 groups: (i) Group A patients received 1 session of RESWT per week for 3 consecutive weeks; (ii) group B patients received a single session of RESWT; and (iii) group C patients received 1 session of sham RESWT per week for 3 consecutive weeks. The primary outcome was Modified Ashworth Scale of hand and wrist, whereas the secondary outcomes were Fugl-Meyer Assessment of hand function and wrist control. Evaluations were performed before the 1st RESWT treatment and immediately 1, 4, 8, 12, and 16 weeks after the last session of RESWT. Compared to the control group, the significant reduction in spasticity of hand and wrist lasted at least 16 and 8 weeks in group A and B, respectively; 3 sessions of RESWT had a longer-lasting effect than 1 session. Furthermore, the reduction in spasticity after 3 sessions of RESWT may be beneficial for hand function and wrist control and the effect was maintained for 16 and 12 weeks, respectively. The authors concluded that RESWT may be valuable in decreasing spasticity of the hand and wrist with accompanying enhancement of wrist control and hand function in chronic stroke patients. These preliminary findings need to be validated by well-designed studies.

Subacromial Shoulder Pain:

Kvalvaag et al (2015) noted that subacromial shoulder pain is a common complaint; RESWT has been increasingly used to treat calcific and non-calcific tendinosis, although there is no evidence of the effectiveness of RESWT in non-calcific tendinosis of the rotator cuff. A randomized, single-blind study showed that the short-term effect of supervised exercises (SE) was significantly better than RESWT on subacromial shoulder pain, but both groups improved. In a clinical trial on Achilles tendinopathy, RESWT improved the effectiveness of treatment with eccentric loading. These investigators examined if RESWT in addition to SE is more effective in improving shoulder pain and function compared with sham RESWT and SE in patients with subacromial shoulder pain. This is a double-blind,
randomized sham-controlled trial that is performed at the shoulder clinic at the Department of Physical Medicine and Rehabilitation in Oslo University Hospital, Norway. A total of 144 patients with subacromial shoulder pain lasting at least 3 months, aged from 25 to 70 years are included in the trial. Patients are randomly allocated in 1:1 ratio to receive either RESWT or sham RESWT once-weekly in addition to SE once-weekly for the initial 4 weeks. Subsequently SE are provided twice-weekly for 8 weeks. The primary outcome measure is a change in the Shoulder Pain and Disability Index (SPADI) at 24 weeks follow-up; secondary outcomes include return to work, pain at rest and on activity, function, and health-related quality of life. The patients, the physiotherapist providing the exercise regimen and the outcome assessor are blinded to group assignment. The physiotherapist providing the RESWT is not blinded. The authors concluded that because of the extensive use of RESWT in the treatment of subacromial shoulder pain the results of this trial will be of importance and have impact on clinical practice.

CPT Codes / HCPCS Codes / ICD-10 Codes

Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":

ICD-10 codes will become effective as of October 1, 2015:

CPT codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0019T</td>
<td>Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy</td>
</tr>
<tr>
<td>0101T</td>
<td>Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy</td>
</tr>
</tbody>
</table>

CPT codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0102T</td>
<td>Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>0299T</td>
<td>Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound</td>
</tr>
<tr>
<td>+0300T</td>
<td>Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; each additional wound (List separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>28890</td>
<td>Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met:**

- M75.30 – M75.32 Calcifying tendinitis of shoulder [Calcific tendinopathy of the shoulder of at least 6 months duration with calcium deposit of 1 cm or greater, and who have failed to respond to appropriate conservative therapies]

**ICD-10 codes not covered for indications listed in the CPB (not all inclusive):**

- F52.21, F52.9 Sexual dysfunction
- L89.200 - L89.229, L89.301 - L89.329, L89.500 - L89.629 Pressure ulcer of hip, buttock, ankle or heel
- L97.100 - L97.929 Non-pressure chronic ulcer of lower limb, not elsewhere classified
- M20.40 – M20.42 Other hammer toe(s) (acquired)
- M25.511 - M25.529 M25.571 - M25.579 Pain in joint of shoulder, elbow, or ankle and foot
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>M25.711 -</td>
<td>Other affections of shoulder region [subacromial impingement syndrome]</td>
</tr>
<tr>
<td>M25.719,</td>
<td></td>
</tr>
<tr>
<td>M75.30 -</td>
<td></td>
</tr>
<tr>
<td>M75.42,</td>
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<td>M75.80 -</td>
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<tr>
<td>M75.92</td>
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<tr>
<td>M48.40x+ -</td>
<td>Stress fracture</td>
</tr>
<tr>
<td>M48.48x+</td>
<td></td>
</tr>
<tr>
<td>M84.30x+</td>
<td></td>
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<tr>
<td>M84.379</td>
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<tr>
<td>M50.00 -</td>
<td>Cervical disc disorder with myelopathy</td>
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<td>M50.03</td>
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<tr>
<td>M50.20 -</td>
<td>Intervertebral disc displacement</td>
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<tr>
<td>M50.23,</td>
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<tr>
<td>M51.24 -</td>
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<td>M51.27</td>
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<tr>
<td>M51.04 -</td>
<td>Thoracic, thoracolumbar and lumbosacral intervertebral disc disorders with</td>
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<tr>
<td>M51.07</td>
<td>myelopathy</td>
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<tr>
<td>M54.14 -</td>
<td>Radiculopathy, thoracic, thoracolumbar, lumbar and lumbosacral region</td>
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<td>M54.17</td>
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<tr>
<td>M54.30 -</td>
<td>Sciatica with/without lumbago</td>
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<td>M54.42</td>
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<tr>
<td>M54.5</td>
<td>Low back pain [lumbago]</td>
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<tr>
<td>M65.871 -</td>
<td>Other synovitis and tenosynovitis, ankle and foot</td>
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<td>M65.879</td>
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<tr>
<td>M72.2</td>
<td>Plantar fascial fibromatosis</td>
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<tr>
<td>M75.00 -</td>
<td>Adhesive capsulitis of shoulder</td>
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<tr>
<td>M75.02</td>
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<tr>
<td>M75.100 -</td>
<td>Rotator cuff syndrome of shoulder and allied disorders [covered for calcific</td>
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<tr>
<td>M75.22,</td>
<td>tendinopathy of the shoulder of at least 6 months’ duration with calcium</td>
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<tr>
<td>M75.40 -</td>
<td>deposit of 1 cm or greater, and who have failed to respond to appropriate</td>
</tr>
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<td>M75.92</td>
<td>conservative therapies]</td>
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<tr>
<td>M76.50 -</td>
<td>Patellar tendinitis</td>
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<td>M76.52</td>
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<tr>
<td>Code</td>
<td>Description</td>
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<tr>
<td>M76.60 -</td>
<td>Achilles bursitis or tendinitis</td>
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<td>M76.811 -</td>
<td>Tibial tendinitis</td>
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<td>M77.00 -</td>
<td>Medial and lateral epicondylitis</td>
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<td>M77.12</td>
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<td>M77.30 -</td>
<td>Calcaneal spur</td>
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<td>M77.9</td>
<td>Enthesopathy, unspecified</td>
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<td>N48.6</td>
<td>Induration penis plastica [Peyronie's disease]</td>
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<td>N52.01 -</td>
<td>Male erectile dysfunction</td>
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<td>N52.9</td>
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<tr>
<td>Numerous</td>
<td>Malunion and nonunion of fracture</td>
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<td>options</td>
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<tr>
<td>Numerous</td>
<td>Open Wounds</td>
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<tr>
<td>options</td>
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<tr>
<td>Q66.89</td>
<td>Other specified congenital deformities of feet</td>
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<td></td>
<td>[Hammer toe]</td>
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<tr>
<td>R25.0 -</td>
<td>Abnormal involuntary movements [spasticity</td>
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<tr>
<td>R25.9</td>
<td>following brain injury]</td>
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<tr>
<td>R29.898</td>
<td>Other symptoms and signs involving the</td>
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<tr>
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<td>musculoskeletal system</td>
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<td>S06.0x0+ -</td>
<td>Intracranial injury</td>
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<td>S06.9x9+</td>
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<tr>
<td>S12.000+ -</td>
<td>Fracture of vertebral column.</td>
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<td>S12.691+,</td>
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<tr>
<td>S22.000+ -</td>
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<td>S22.089+,</td>
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<td>S32.000+ -</td>
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<td>S32.2xx+</td>
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<tr>
<td>Code</td>
<td>Description</td>
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<tr>
<td>S14.101+</td>
<td>Spinal cord injury</td>
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<td>S14.159+,</td>
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<td>S24.101+</td>
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<tr>
<td>S24.159+,</td>
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<tr>
<td>S34.101+</td>
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<tr>
<td>S34.139+</td>
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<tr>
<td>T20.20x+</td>
<td>Burn of second and third degree of face, head, and</td>
</tr>
<tr>
<td>T20.39x+</td>
<td>neck</td>
</tr>
<tr>
<td>T20.60x+</td>
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<tr>
<td>T20.79x+</td>
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<tr>
<td>T21.20x+</td>
<td>Burn of second and third degree of trunk</td>
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<tr>
<td>T21.39x+</td>
<td></td>
</tr>
<tr>
<td>T21.60x+</td>
<td></td>
</tr>
<tr>
<td>T21.79x+</td>
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</tr>
<tr>
<td>T22.20x+</td>
<td>Burn of second and third degree of upper limb,</td>
</tr>
<tr>
<td>T22.399+</td>
<td>except wrist and hand</td>
</tr>
<tr>
<td>T22.60x+</td>
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</tr>
<tr>
<td>T22.799x+</td>
<td></td>
</tr>
<tr>
<td>T23.201+</td>
<td>Burn of second and third degree of wrist and hand</td>
</tr>
<tr>
<td>T23.399+</td>
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<tr>
<td>T23.601+</td>
<td></td>
</tr>
<tr>
<td>T23.799+</td>
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</tr>
<tr>
<td>T24.201+</td>
<td>Burn of second and third degree of lower limb,</td>
</tr>
<tr>
<td>T24.399+</td>
<td>except ankle and foot</td>
</tr>
<tr>
<td>T24.601+</td>
<td></td>
</tr>
<tr>
<td>T24.799+</td>
<td></td>
</tr>
<tr>
<td>T25.211+</td>
<td>Burn of second and third degree of ankle and foot</td>
</tr>
<tr>
<td>-T25.399+</td>
<td></td>
</tr>
<tr>
<td>T25.611+</td>
<td></td>
</tr>
<tr>
<td>-T25.799+</td>
<td></td>
</tr>
<tr>
<td>Z87.312</td>
<td>Personal history of (healed) stress fracture</td>
</tr>
</tbody>
</table>

The above policy is based on the following references:

1. National Health Service (UK). Are depo-medrone and/or
other corticosteroids effective for lateral epicondylitis (tennis elbow)? Are there other effective treatments?


32. Rompe JD, Zoellner J, Nafe B. Shock wave therapy versus conventional surgery in the treatment of calcifying...


67. National Institute for Health and Clinical Excellence


86. Ham P, Maughan KL. Achilles tendinopathy and tendon rupture. Last reviewed May 2013. UpToDate Inc. Waltham, MA.
87. Buchbinder R. Plantar fasciitis and other causes of heel pain. Last reviewed May 2013. UpToDate Inc. Waltham, MA.


110. Caron J, Michel PA, Dussaule JC, et al. Extracorporeal shock wave therapy does not improve hypertensive


Amendment to
Aetna Clinical Policy Bulletin Number: 0649
Extracorporeal Shock-Wave Therapy for Musculoskeletal
Indications and Soft Tissue Injuries

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania
Updated 03/2017