Anthem

Medical Policy

Subject: Extracorporeal Shock Wave Therapy
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Description/Scope

This document addresses the use of extracorporeal shock wave therapy (ESWT), including Extracorporeal Pulse Activation Therapy (EPAT®), for the treatment of musculoskeletal conditions, soft tissue injuries, and erectile dysfunction.

Note: This document does not address extracorporeal shock wave lithotripsy.

Position Statement

Investigational and Not Medically Necessary:

Use of Extracorporeal Shock Wave Therapy (ESWT), including but not limited to the use of Extracorporeal Pulse Activation Therapy (EPAT®), for the treatment of musculoskeletal conditions and soft tissue injuries is considered**investigational and not medically necessary.** These conditions include, but are not limited to:

- Chronic plantar fasciitis
- Calcified tendinitis of shoulder
- Chronic lateral epicondylitis (tennis elbow)
- Elbow tendinitis
- Erectile dysfunction
- Fixation of loosened cemented orthopedic prosthesis
- Non-union fractures
- Peyronie's disease
- Soft tissue or wound repair

Rationale

Plantar fasciitis

Evidence in the form of randomized controlled trials (RCT) regarding the efficacy of extracorporeal shock wave treatment (ESWT) for plantar fasciitis is conflicting. A trial by Buchbinder, published in 2002 in the Journal of the American Medical Association (JAMA), reported no significant difference between individuals with plantar fasciitis treated with low energy ESWT vs. placebo. Concerns about the selection criteria used for this study have been raised, asserting that individuals who participated in the study failed to have long-standing conditions, nor did they fail any previous therapies. A study, also of a low energy device, was in the form of unpublished data submitted to the U.S. Food and Drug Administration (FDA) by Dornier Medical Systems Inc., a manufacturer of the EPOS UltraÒ ESWT device. In that study, a small but statistically significant improvement was noted in subjective pain ratings and on a standardized foot scoring tool in the experimental group. No other significant differences were noted between the experimental and placebo groups. Of note, the study's blinding may have been ineffective in that 59% of the experimental group vs. 15% of participants in the placebo group correctly identified their treatment group; bias favoring treatment must be considered.

Additional peer-reviewed journal articles continue to produce conflicting results. Randomized, placebo controlled, double-blinded studies by Haake (2003), Rompe (2003), and Speed (2003) all evaluated the efficacy of this therapy with low energy devices for the treatment of plantar fasciitis. While the Rompe study found a significant benefit to these devices, the Haake and Speed studies found the devices to be ineffective when compared to placebo treatments. The medical evidence remains unclear regarding the benefits of low energy ESWT for plantar fasciitis.

An RCT study reporting on the use of ESWT for plantar fasciitis was published in 2001 by Ogden and colleagues. This study reported a significant benefit of high energy ESWT. Two randomized placebo-controlled, but non-blinded trials of high energy ESWT devices demonstrated a significant benefit of high energy ESWT for plantar fasciitis (Alvarez, 2003; Lee, 2003). The lack of adequate participant blinding is an important source of bias and conclusions that these treatments are effective cannot be reasonably drawn.

Gollwitzer and colleagues (2007) published the results of a prospective, double-blind, randomized, placebo-controlled trial involving 40 individuals with plantar fasciitis. Participants were randomly assigned to receive either extracorporeal shock wave therapy or sham shock wave therapy. Treatments were given 1 week apart for 3 weeks and the final follow-up was 12 weeks after the last treatment. The authors reported that there was a 73.2% reduction in composite heel pain in the experimental group, and that this was 32.7% greater than the results achieved in the placebo group. However, the authors reported this difference was not statistically significant.

A double-blind RCT by Malay (2006) provided active ESWT to 115 participants and placebo to 57. The authors report that both blinded observer and self-reported assessments of heel pain were significantly better in the treatment group. A significant limitation of this study is that the researchers did not utilize formal standardized quality of life or foot scoring systems, nor did they collect data on participants past 3 months post-treatment.

Two studies of low energy devices, both placebo-controlled, double-blind clinical trials (Kudo, 2006; Porter, 2005) have conflicting conclusions, with the Kudo article supportive of ESWT when compared to placebo, and the Porter article finding that ESWT was not more efficacious than corticosteroid therapy. Additionally, Rompe et al. published the findings of a single-blind RCT comparing low energy treatment to plantar fascia-specific stretching exercises in 82 subjects (2010). The authors reported finding no significant differences between the two groups, at 15 months.

A systematic review and meta-analysis by Thompson (2005) reviewed six RCTs which included a total of 897 individuals. Their analysis concluded that ESWT does provide some beneficial effects, but that the treatment effects are very small.

In 2012, Radwan and colleagues published their findings from a non-blinded RCT. In this study, 65 subjects were randomized to undergo treatment with endoscopic plantar fasciotomy (n=31) vs. high energy ESWT (n=34) and followed for 12 months. The authors

reported no significant differences between treatment groups with the exception of the American Orthopedic Foot and Ankle-hindfoot Scale (AOFAS) maximum walking distance and gait sub-scores at 3 weeks. This difference was not durable and disappeared at subsequent time points. They also reported that at 2- and 3-year follow-up times, subjects were contacted regarding perceived success of their interventions. At 2 years, 50% (13/26) of the ESWT group and 80% (20/25) of the fasciotomy group felt their procedure was a success (p=0.026). At 3 years, these numbers changed to 47% (11/23) vs. 80% (20/25) respectively (p=0.021). To date, the published evidence regarding ESWT for plantar fasciitis continues to be contradictory.

Two systematic reviews and meta-analyses of RCTs were published in 2013 (Aquil, 2013; Dizon, 2013). Both reported that ESWT is better than or comparable to placebo in reducing pain and improving functional status in the short-term. However, many limitations exist in interpreting these findings, including inconsistent results and heterogeneity in the studies that sometimes precluded meta-analysis of pooled data. Additionally, significant variation between the included studies with regard to dose intensities, type of shockwaves used, and frequency of treatments limited the conclusions which could be drawn from these studies. Finally, given plantar fasciitis often resolves within a 6-month time period, longer follow-up studies are needed to compare ESWT results to the natural resolution of the condition. The clinical significance of results reported at shorter follow-up, such as 3 months, is uncertain.

In 2014, Yin and colleagues published a systematic review and meta-analysis of studies involving ESWT for plantar fasciitis. The authors included a total of seven studies that were either RCTs or quasi-RCTs involving subjects with plantar fasciitis of at least 6 months duration. The primary outcome was treatment success rate. Among the five studies included in the pooled analysis for low energy devices, the result indicated that low energy ESWT was more likely to lead to treatment success than control treatment (p<0.001). 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.

Gollwitzer 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%, p=0.0027, one-sided). They also stated that the ESWT group demonstrated significantly superior results on the Roles and Maudsley score, a subjective 4-point patient assessment of pain and limitations of activity (p=0.0006, one-sided). No test for the accuracy of the blinding was conducted.

In 2017, two meta-analyses were published involving the same nine studies, all of which have been addressed above (Lou, 217, Sun, 2017). While both of these studies concluded that ESWT was effective for the treatment of recalcitrant plantar fasciitis, the same limitations noted above apply to this data.

Lai and others (2018) published the results of a single-blind RCT involving 97 subjects with plantar fasciitis treated with either ESWT or corticosteroid injections. The authors reported that at 12 weeks, significant differences between groups in favor of the ESWT group were found on pain visual analog scale measures (VAS) and 100-point score (p<0.01). The tool used to assess the 100-point score was not specified, other than to indicate that 70 points of the scale were for pain and 30 were for “functional scores”. Both the VAS and 100-point measure were primarily subjective based on unblinded subject response. The authors also reported on evaluator-blinded plantar fascial thickness as measured by ultrasound. They reported that plantar fascial thickness increased more in the ESWT group vs. the injection group, with marginal significance (p=0.48). However, this difference was not significant at 12 weeks. Overall, these findings are of questionable value, given the use of subjective measures and lack of significant differences in plantar fascial thickness at 12 weeks.

In 2017 the American College of Foot and Ankle Surgeons released a consensus statement for the diagnosis and treatment of adult acquired infracalcaneal heel. This document includes the statement, “Extracorporeal shockwave therapy (ESWT) is safe and effective in the treatment of plantar fasciitis”. However, 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.

Overall, there is conflicting evidence regarding the benefits of ESWT for plantar fasciitis. Significant questions remain that warrant investigation in a large, well designed and conducted double-blind RCT.

Epicondylitis

ESWT has also been proposed as a treatment for lateral epicondylitis (tennis elbow). Recent systematic reviews and meta-analyses (Bisset, 2005; Buchbinder, 2005 and 2006) conclude that ESWT for tennis elbow does not provide significant clinical benefit. The Buchbinder studies go further, concluding that there is good evidence to demonstrate that corticosteroid injection may be more effective than ESWT treatment.

A systematic review of the available RCTs addressing the efficacy and safety of extracorporeal shock wave therapy (ESWT) for lateral elbow pain was published in the Journal of Rheumatology (Buchbinder, 2006). This study utilized Cochrane Collaboration methodology in evaluating nine placebo-controlled trials and one steroid injection controlled trial. The authors note that the nine placebo-controlled trials reported conflicting results, although 11 of 13 pooled analyses found no significant benefit of ESWT over placebo. Two of the included studies favored ESWT. It was noted by the authors that the results of four other trials not included in the pooled results found no benefit to ESWT as well. The result of the systematic review indicates that steroid injection was more effective than ESWT at 3 months after the end of treatment, and only minimal adverse effects of ESWT were reported. The conclusion of the study was:

> There is "platinum" level evidence that ESWT provides little or no benefit in terms of pain and function in lateral elbow pain. There is "silver" level evidence based upon one trial that steroid injection may be more effective than ESWT.

Radwan and colleagues (2008) presented the results of a small RCT of ESWT for epicondylitis (n=29) vs. percutaneous tenotomy (n=26). The results reported at 12-month follow-up found no significant difference between groups in terms of success rate, as measured by score on the Thomsen test. This is the first published report comparing ESWT to surgical intervention. Further data from larger trials would be helpful in understanding these results. An article describes the results of a double-blind randomized placebo-controlled trial of ESWT for epicondylitis (Staples, 2008). This study involved 68 individuals assigned to either ESWT or sham treatment. The authors reported that at the 6-month follow-up visit, there were significant improvements in both groups, but no significant differences between groups even after adjusting for duration of symptoms.

In a 2013 systematic review and meta-analysis, Ioppolo et al. included six RCTs on ESWT compared to sham treatment or placebo for calcific shoulder tendinopathy. Greater shoulder function and pain improvements were found at 6 months with ESWT over placebo. However, most studies were considered to be low quality.

Aydın and Atiç (2018) reported the results of a single-blind RCT comparing radial ESWT vs. wrist-extensor splints (WES) in 67

subjects with unilateral lateral epicondylitis. ESWT was administered to 32 subjects and WES were worn by 35 subjects. The authors reported significant improvements in both groups with regard to VAS pain scores while at rest and while working, grip strength, and scores on both the Patient-Related Tennis Elbow Evaluation assessment (PRTEE-T) and the Nirschl function scale. However, no significant differences were reported between treatment groups.

Guler and collegues (2020) evaluated the efficacy of kinesiotaping (KT) and ESWT for 40 individuals (27 females and 13 males) with newly diagnosed acute/subacute (complaints exist < 3 months) lateral epicondylitis (LE). Study participants were randomly allocated to receive a 3-week treatment of either KT for 5 days a week (n=20) or ESWT once a week (n=20). Subjects were evaluated using hand grip strength (HGS), visual analog scale (VAS), Roles and Maudsley scale (RMS), and quick DASH questionnaire at baseline. Assessments were completed after 4 weeks, and after 8 weeks of the treatment. Measures evaluated included pain control, hand grip strength, and functionality. The authors reported both KT and ESWT could achieve significant improvements in VAS, HGS, RMS, and Q-Dash after 4 and 8 weeks of treatment. However, these improvements were more noticeable in the KT group compared with ESWT after 4 and 8 weeks. Compared with ESWT, the KT cohort achieved lower VAS scores, higher HGS, lower RMS compared with ESWT (all $p<0.05$). The authors proposed that due to low cost and feasibility of KT compared with ESWT, that KT should be considered for treating individuals with newly diagnosed LE. The authors acknowledged that limitations of the study designed include the relatively small sample size and the limited (8 weeks) follow-up. Additional studies evaluating the long-term outcomes of KT and ESWT in larger samples are still needed to confirm these findings.

Also in 2020, Zheng and colleagues (2020) presented the results of a meta-analysis of RCTs to investigate the effectiveness of ESWT as a treatment for lateral epicondylitis of humerus. A total of nine studies were included in the meta-analysis. The primary outcome was the mean overall pain score at 12 weeks after treatment. Secondary outcomes included Thomsen test, 50% pain reduction, grip strength and adverse effect at 12 weeks after treatment. The authors concluded that compared with the placebo group, ESWT cannot significantly reduce the pain score (mean deviation [MD] = -4.23; 95% confidence interval [CI], -8.78 to 0.32; $p=0.07$), but can make more individuals acquire 50% pain reduction (MD=1.38; 95% CI, 1.09 to 1.75; $p=0.008$). There was no significant difference between the ESWT cohort and the control group in reducing the pain score of Thomsen test (MD = -3.22; 95% CI, -14.06 to 7.62, $p=0.56$). ESWT proved to be more effective in Grip strength as compared with control at 12 weeks-3 months (MD=3.52; 95% CI, 2.43 to 4.60; $p<0.00001$). The authors concluded that while ESWT cannot effectively reduce the mean overall pain, it demonstrated that more people acquire 50% pain reduction and might be a better option for the treatment of LE. A limitation of the study includes the large degree of heterogeneity amongst the studies. Some of the studies assessed the use of focused waves while others used radial waves. The studies also varied in the duration and frequency of treatment as well as the strength and length of waves and number of shocks delivered during a treatment session. Due to the large heterogeneity of the studies included in the analysis, it difficult to draw conclusions regarding the efficacy of ESWT treatment. The authors acknowledged that additional rigorously designed large-samples and high-quality randomized controlled trials are needed to guide clinical practice.

These results are interesting, but the majority of available studies contain significant flaws limiting their generalizability. Further investigations are needed to fully understand the safety and efficacy of ESWT for lateral epicondylitis.

Shoulder Conditions

To date, the majority of studies on the use of ESWT for the treatment of shoulder tendinitis are limited by small sample size and flawed study design. The study by Cosentino (2001), while demonstrating good clinical response to ESWT, is only single-blinded and includes only 70 participants. Similarly, the Pan study (2003) includes 60 participants and does not specify the degree of blinding, which hampers the ability to fully weigh the benefits of the study objectively. As with any study of a pain syndrome, large-scale, randomized double-blind, placebo-controlled design is the most effective in isolating placebo effect and minimizing confounding factors. One such study by Gerdesmeyer (2003) found significant benefits of both low- and high-powered ESWT devices in the treatment of shoulder tendinitis when compared to placebo treatment with a follow-up of 12 months. While this evidence is promising, the authors comment that their findings need to be confirmed by further studies.

In 2013, Kolk and colleagues published the results of an RCT in which 82 subjects with chronic tendinitis were assigned to receive treatment with either low-dose radial ESWT (n=44; 3 sessions at an interval 10 to 14 days, 2000 pulses, 0.11 mJ/mm^2, 8 Hz) or placebo (n=38). The follow-up period was 6 months. Both the subjects and the evaluating surgeon were blinded to the treatment assignment. The authors reported that the visual analog scale VAS score for pain, Constant-Murley score (CMS), and a Simple Shoulder Test (SST) were all significantly improved in both groups at 3 and 6 months compared with baseline ($p\leq0.012$). The mean VAS was similar in both groups at 3 ($p=0.43$) and 6 months ($p=0.262$). They concluded that low-dose radial ESWT did not reduce pain or improve function in subjects with chronic rotator cuff tendinitis.

A small RCT by Kim et al. (2014) compared ultrasound guided corticosteroid injections to ESWT in a group of 62 subjects with shoulder tendinitis. A total of 54 (87%) subjects completed an average 24 months in the follow-up period. While the radiologic evaluations were blinded, it is not clear whether or not the clinical evaluations were blinded as well. At the last follow-up, it was reported that the calcium deposits had decreased in size significantly more in the ESWT group ($p=0.001$). However, at 1 year, functional outcomes were reported to be significantly better in the corticosteroid group on the American Shoulder and Elbow Surgeons assessment ($p=0.001$), SST ($p=0.015$), and visual analog scale ($p=0.003$). The authors concluded that corticosteroid injections are more effective than ESWT.

Verstraelen and colleagues published a meta-analysis of studies comparing high energy vs. low energy ESWT for shoulder tendinitis (2014). The analysis involved five studies totaling 359 subjects. Three of the included trials were considered high quality. The authors reported that high energy ESWT, when compared to low energy ESWT, provided significantly more improvements in functional outcomes ($p<0.001$). They added that high energy ESWT was more likely to provide resolution of calcium deposits at 3 months ($p=0.009$).

In 2017 Wu and colleagues reported the results of a network meta-analysis on the available evidence addressing various non-operative treatments for chronic calcific tendinitis of the shoulder. A total of 14 studies involving 1105 subjects were included. Of the studies included, 2 compared echo-guided needling to radial ESWT (Lou, 2017, Sun, 2017), 6 studies compared high frequency ESWT to low frequency ESWT, 1 study compared high frequency ESWT to TENS, 4 studies compared high frequency ESWT to a control group, and 1 study compared radial ESWT to a control group. Quality pain reduction data was available in 8 studies, and a weight mean difference in visual analog scale reduction was 2.43 for high frequency ESWT vs. low frequency ESWT. The odds ratio (OR) of complete resolution was 2.14 for high frequency ESWT vs. low frequency ESWT, 6.06 for high frequency ESWT vs. control treatment, 68.7 for radial ESWT vs. control treatment, and 1.78 for low frequency ESWT vs. control treatment. Analysis of complete calcification resorption involved 14 studies, and the odds ratio, vs. controls was 6.84 for radial ESWT, 2.42 for high frequency ESWT, and 1.18 for low frequency ESWT. Analysis of functional improvement involved 7 studies, and resulted in a finding that high frequency ESWT was the most effective treatment (OR, 25.14). This meta-analysis involved the studies previously described above, which have significant methodological shortcomings.

A double-blind RCT involving 143 subjects with subacromial shoulder pain treated with either radial ESWT or sham ESWT was reported by Kvalvaag in 2018. Active ESWT was provided to 74 subjects and sham to 69, with 66 (89%) active and 64 (03%) sham

subjects completing the 1-year follow-up period. At the completion of the study the authors reported no differences between groups with regard to treatment effect as measured by the Shoulder Pain and Disability Index (SPADI). Significant reduction in SPADI scores was seen in 53.6% of ESWT subjects and 51.4% of sham subjects (p=0.89). Additionally, no differences between groups were reported with regard to pain, function, shoulder-related sick leave, quality of life, or subsequent additional treatments.

These results are interesting, but are based on data from studies with significant flaws. Further investigations are needed to fully understand the safety and efficacy of ESWT for shoulder tendinitis.

In another study, Surace and colleagues (2019) published the results of a systematic review that examined the benefits of ESWT for rotator cuff disease, with or without calcification. The authors included RCTs and controlled clinical trials (CCTs) that used quasi-randomized methods to allocate subjects. Trials included were those that compared ESWT to any other intervention. The authors found that the available studies demonstrated few clinically significant benefits of shock wave therapy, and uncertainty regarding its safety. Varying treatment protocols and wide clinical diversity protocols prevented the authors from determining whether or not some trials tested subtherapeutic doses, possibly underestimating any potential benefits. The authors recommended that researchers conduct additional clinical trials of ESWT for rotator cuff disease based upon a strong rationale and consideration of whether or not they would alter the conclusions of this review. Additionally, the authors recommended that a standard dose and treatment protocol be decided upon before further research is conducted. Lastly, the authors recommended that a core set of outcomes for trials of rotator cuff disease be developed in order to facilitate the synthesis of the evidence.

Erectile Dysfunction (ED)

Low-intensity ESWT (LiESWT or LiSWT) has been proposed as a treatment for ED. In 2019, Campbell and colleagues published a systematic review and meta-analysis that assessed the efficacy of LiESWT for the treatment of ED. The authors included seven RCTs (n=607) published up to July 2018 that were conducted in multiple countries. The primary outcome was the mean difference between treatment and sham based on the International Index of Erectile Function-Erectile Function (IIEF-EF) domain score. The pooled trial data was considered to have a low risk of bias. A total of six trials, all with significant heterogeneity, provided data on the mean IIEF-EF at 1 month. The mean IIEF-EF at 1 month ranged from 12.8 to 22.0 in the treatment group compared to 8.17 to 16.43 in the sham group, for a mean difference between the groups of 4.23 (95% CI, 0.94 to 7.53; p=0.012). For five out of seven trials that included data on the erectile hardness score (EHS), the pooled relative risk of EHS improvement for the treated versus sham group was 6.63 (95% CI, 1.59 to 27.71; p=0.0095). Adverse events were mild and included a slight burning sensation and local irritation. The authors noted that future high-quality RCTs with uniform reporting and long-term follow-up are needed to evaluate the efficacy of LiESWT for ED. Studies are also needed to substantiate dose dependency and an optimal treatment schedule.

In a systematic review, Brunckhorst and colleagues (2019) evaluated the long-term efficacy of LiSWT for vasculogenic ED. They included 11 studies (n=799), including 5 RCTs and 6 nonrandomized studies, published up to September 2018. Outcome measures included the IIEF-EF score and the EHS. Nine studies found a significant increase in ED scores, with a median IIEF-EF score improvement of 5.3 at 6 months. Two RCTs did not reach the set threshold for significance at follow-ups over 6 months. There was an overall limited improvement in IIEF-EF scores over 6 months, and no studies found ongoing improvement at 12 months. At 12 months there was either plateauing or reduction in functional outcomes. The authors recommend further investigation through larger and more standardized trials.

Bakr and colleagues (2021) published the results of a systematic review that examined the effects of ESWT on penile deviation, plaque size, erectile function, pain, and the rate of complications in individuals with Peyronie's disease. Meta-analysis and forest plots were carried out using RevMan, and outcomes were evaluated by 2 authors independently. PRISMA guidelines were utilized to achieve the quantitative and qualitative synthesis of data. Changes in penile deviation, plaque size, erectile function, pain scale, and the rate of ESWT related complications were captured. The authors identified a total of 73 articles. Three RCTs, including 117 subjects in the ESWT group and 121 participants in the placebo group, were reviewed. ESWT was associated with reduction in plaque size (OR=2.59, 95% CI (1.15-5.85), p=0.02). No significant difference in rate of bruises or reduction of penile deviation angle were detected in the post ESWT group when compared to placebo. The authors concluded that a review of the evidence did not demonstrate an effect of ESWT on erectile function or pain scale. The authors also concluded that while ESWT may reduce plaque size, this remains of questionable clinical significance and additional studies are required to confirm findings.

In a guideline on ED (Burnett, 2018), the American Urology Association (AUA) stated the following:

> For men with ED, low-intensity extracorporeal shock wave therapy (ESWT) should be considered investigational. (Conditional Recommendation; Evidence Level: Grade C)

In a position statement on ED restorative therapies (Liu, 2021), the Sexual Medicine Society of North America (SMSNA) provides the following summary of the peer-reviewed evidence on liSWT for ED:

> Collectively, the cumulative results from the LiSWT clinical trials suggest a promising degree of efficacy and are encouraging for this technology. Importantly, across all trials, there were no documented adverse events with various LiSWT treatment protocols. Thus, at bare minimum LiSWT, within the parameters of studies performed, is safe. However, the shockwave generator types and protocols (energy settings, dosing, frequency of use, probe locations, and duration of therapy) were inconsistent between studies and consequently difficult to compare. Looking at the studies, most patient cohorts are small and heterogeneous, further complicating any type of comparison. Even in studies where patients have similar sources of ED (ie, prostatectomy) underlying comorbidities such as diabetes, age, and vascular disease makes randomization and patient grouping challenging. A major limitation to most LiSWT studies is the lack of randomization to a sham control cohort. A number of studies have performed randomization and provided sham controls (ie, identical treatment protocols without shocks) and blinding both patients and providers, whenever possible. Blinding providers is especially important since end-point analysis often included functional surveys like EHS, IIEF, and SHIM. Therefore, clinical trials exploring the types of shockwave, utilization of sham control cohorts, and comparing patient populations would be very helpful in further identifying ideal treatment candidates and true ability to use this restorative therapy for management of ED. Likewise, more studies with variable protocols are needed to find the ideal dosing for maximal effect. Similarly, given the broad spectrum of treatment protocols future clinical trials should attempt to provide some standardization in both device settings (measured in total energy of treatment or EFD) as well as duration of treatment (6 months, 1 year, or greater).

While short-term benefits are promising, there is a lack of data demonstrating the long-term safety and efficacy of LiESWT for ED.

Other Indications

ESWT has been proposed for a wide range of other conditions. For most of these conditions, no RCTs have been published, but some limited evidence has been made available. A study by Caccio and colleagues (2009) reports on the use of ESWT for the treatment of long bone non-unions. In this study, 126 participants with long bone non-unions were randomized to receive either: (1)

low energy ESWT; (2) high energy ESWT; or (3) surgical management. The authors reported that at 3 and 6 months post-treatment the clinical outcomes in the 2 shock wave groups were significantly better than those in the surgical group (p<0.001). However, at 24 months after treatment, there were no differences among the 3 groups.

Lui presented the findings from a sham-controlled RCT of 90 subjects with bicipital tenosynovitis treated with radial ESWT (2012). Of the 90 subjects starting the study, 79 (87%) completed the 12-month follow-up period (n=34 ESWT, n=18 Control). At 1 month post-treatment, 32 ESWT subjects received evaluation with ultrasound (US) with 27 reverting to normal. At the same time point, 18 control subjects received US evaluation with 15 reporting no changes. The results of VAS pain scale indicated significant improvement for the ESWT group vs. controls at all time points. Similar benefits were reported for the ESWT group vs. the control group with regard to the L'Insalata shoulder questionnaire. No significant complications were reported. This study is hampered by unequal numbers of subjects in each group, no blinding, and only subjective survey tool data from follow-up calls.

An RCT was conducted by Seok (2013) comparing one session of ESWT (1000 shots at the maximal tolerable intensity) vs. one session of local corticosteroid injection in 36 subjects with carpal tunnel syndrome. Follow-up was at 3 months post-treatment. The results indicated that both groups showed a significant reduction in the visual analog scale measurements at 1 and 3 months compared with baseline. For the symptom severity score, as measured by the Levine Self-assessment Questionnaire, the ESWT group showed a significant reduction at 1 and 3 months, whereas the injection group showed a significant reduction only at 3 months following treatment. Nerve conduction parameters were not significantly improved in the ESWT group, whereas the sensory nerve conduction velocity, the sensory nerve action potential amplitude, and the distal sensory and motor latencies of the median nerve were significantly improved in the injection group. The authors concluded that ESWT may be as useful as local corticosteroid injection for relieving symptoms of carpal tunnel syndrome. However, the results of this small unblinded trial indicate that ESWT is not superior to corticosteroid injection therapy.

Ozturk Durmaz and colleagues (2022) explored the effectiveness of radial ESWT and local corticosteroid injection in individuals with idiopathic carpal tunnel syndrome. The researchers evaluated the impact of treatment on function, pain, and nerve conduction studies. A total of 72 participants who were diagnosed as having carpal tunnel syndrome were included in the study and randomized to receive treatment. One cohort (n=33) received radial ESWT, another cohort (n=28) was treated with local corticosteroid injection (CSI), and the control group (n=31) only used a resting hand splint. A total of 20 subjects (7 ESWT, 5 CSI, and 8 splint) were lost to follow-up. The participants were evaluated using a Visual Analog Scale-pain, a Visual Analog Scale-numbness, the Boston Symptom Severity Scale, the Boston Functional Status Scale, and handgrip strength tests before treatment, and 1 and 12 weeks following the treatment. Primary outcomes were symptom severity and functional status. Secondary outcomes included evaluation of pain and numbness, handgrip strength and electrophysiologic examinations. All three groups demonstrated improvement in clinical and nerve conduction study parameters and this effect persisted at the 12-week follow-up of the participants. The Visual Analog Scale-pain, Visual Analog Scale-numbness, Boston Symptom Severity Scale, and Boston Functional Status Scale scores in the first week after the treatment, as well as Visual Analog Scale-pain and Boston Functional Status Scale scores in the 12th week after the treatment, were notably lower in the local corticosteroid injection group compared with the other two groups. The authors concluded that the ESWT, splint, and local corticosteroid injection are all effective, but symptom relief was greater in the first week and 12th week with local corticosteroid injection.

Zhao and others (2013) conducted a single-blind, placebo controlled RCT of ESWT for the treatment of osteoarthritis of the knee. In this study, 70 subjects were assigned to receive ESWT (n=34) or placebo (n=36). For ESWT, subjects received 4000 pulses of shockwave at 0.25 mJ/mm^2 weekly for 4 weeks. In the placebo group, subjects received shockwave at 0 mJ/mm^2 in the same area. No adverse events were reported. Of the original 70 subjects, 61 (87.1%) subjects completed the study, with no significant difference between groups. The authors state that ESWT was more effective than placebo in reducing pain on movement at each period as measured by visual analog scale (p<0.01). The mean visual analog scale score with ESWT was 3.83 at 12 weeks versus 7.56 at baseline (p<0.01). For the Lequesne index, at 12 weeks, the decrease in disability was almost -2.0 for the placebo group but -4.1 for the ESWT group (p<0.01). Similarly, the mean change in Western Ontario and McMaster University Osteoarthritis Index (WOMAC) score after 12 weeks was -8.5 for the placebo group and -19.1 for the ESWT group (p<0.01). The authors conclude that ESWT is effective in reducing pain and improving knee function, with better results than placebo during the 12-week treatment. Although promising, the results of this small study need to be validated in larger, double-blind controlled trials with longer follow-up to establish a durable treatment effect over placebo.

Li and others (2016) reported on a prospective single-blind, placebo controlled RCT investigating the long-term effect of radial ESWT (rESWT) in subjects with poststroke spasticity. The 60 participants were assigned to 1 of 3 groups: (1) treatment with one session of rESWT per week for 3 consecutive weeks; (2) a single session of rESWT; and (3) one session of sham rESWT per week for 3 consecutive weeks. Evaluations were performed at baseline prior to treatment and 1, 4, 8, 12, and 16 weeks after treatment. Compared to the control group, significant reduction in spasticity of hand and wrist lasted at least 16 and 8 weeks in group 1 and 2, respectively. The authors noted that three sessions of rESWT had a longer-lasting effect than one session. Furthermore, the reduction in spasticity after three sessions of rESWT was maintained for 16 and 12 weeks, respectively. They 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."

Gao and colleagues (2016) conducted a meta-analysis on ESWT for Peyronie's disease. A total of six comparative studies (n=443) were included, including two case-control studies, one cohort study and three RCTs. The researchers found that ESWT lessened penile plaques (OR 2.07; 95% CI, 1.11 to 3.85, p=0.02), relieved pain (OR 4.46; 95% CI, 2.29 to 8.68; p<0.0001) and provided complete remission of pain (OR 5.86; 95% CI, 2.66 to 12.92; p<0.0001). There were no significant improvements in penile curvature (OR 1.88; 95% CI, 0.97 to 3.65; p=0.06) and sexual function (OR 2.22, 95% CI, 0.69 to 7.11; p=0.18). The researchers recommended further high-quality double-blind RCTs to assess the findings.

In 2017, Thijs and others reported on the results of a double-blind RCT involving 32 subjects with patellar tendinopathy who were treated with either ESWT (n=22) or sham therapy (n=30). Subjects were followed for 24 weeks after 3 weekly ESWT treatments. All subjects also conducted twice daily eccentric exercises for 12 weeks post-procedure. All randomized subjects completed the treatment, but loss to follow-up included 7 ESWT subjects (31.8%) and 4 control subjects (13.3%). The authors reported no significant differences between groups with regard to Victoria Institute of Sport Assessment (VISA-P) scores at 24 weeks (p=0.15). These results were consistent in both the intent-to-treat and per-protocol analyses. Additionally, visual analog scores for pain at 6, 12, and 24 weeks were not significantly different (p=0.127, 0.755, and 0.928, respectively).

Zhang and colleagues (2017) performed a systematic review and meta-analysis of RCTs to evaluate ESWT for chronic wounds. The researchers evaluated RCTs published between 2000 and 2017 and included seven trials (n=301) in the analysis. Compared with control, ESWT increased the wound healing rate by 1.86-fold (OR 52.86; 95% CI, 1.63 to 5.03; p=0.0003) and the percentage of the wound healing area by 30.46%. Wound healing time was reduced by 19 days, and no serious adverse events were reported. The researchers concluded more high-quality RCTs are needed to evaluate ESWT for wound healing in clinical practice.

Hurt and colleagues (2020) reported the results of a prospective, randomized, double-blind, placebo-controlled study evaluating the effects of ESWT on vulvodynia. The study included 62 individuals with vulvodynia for at least 3 months. The participants were

randomly assigned to either a treatment group (n=31) or a placebo group (n=31). Individuals in the treatment group underwent perineally applied ESWT weekly (3000 pulses each for 4 consecutive weeks). The researchers used a standard electromagnetic shock wave unit with a focused shock wave handpiece. The position of the shock wave transducer was altered six times after every 500 pulses. Participants in the placebo cohort underwent the same treatment procedure, but the handpiece was provided with a placebo stand-off that disabled energy transmission. Subjective pain was self-evaluated by each participant using two tools before and after treatment: a 10 cm linear visual analogue scale (VAS, 0-10) and a cotton-swab test (CST, Goetsch scale 0-4). Follow-up evaluations were completed at 1, 4, and 12 weeks post-ESWT. One participant was lost to follow-up. All of the remaining 61 participants completed the study. The researchers evaluated the differences in the VAS and CST within and between the treatment and placebo groups. A decrease in VAS ($p<0.01$) and CST ($p<0.01$) were observed at all three follow-ups. At all assessments, pain reduction was always greater than 30%. In the placebo cohort there were no statistically significant changes between before and after treatment. There were no differences between the treatment group and the placebo group prior to treatment but there were statistically significant differences at each of the three follow-up evaluations (VAS $p<0.01$); CST $p<0.01$). The researchers concluded ESWT appears to reduce pain perception in the treated group. A major limitation of this study was its small sample size and the lack of any objective measurements of pain (for example, looking at images of brain scans).

Daia and colleagues (2021) compared the effectiveness of radial ESWT and ultrasound (US) in a group of adult participants with idiopathic scoliosis in terms of pain, disability, and QOL. A total of 48 subjects with idiopathic scoliosis were randomly divided into 3 groups of 16: ESWT, US, and control. Participants were examined at admission (day 1) and at discharge (day 14) for pain, by using the VAS; for disability, by using the ODI; and for the QOL, with short form-36. The researchers found that radial ESWT was more effective than US in reducing pain ($p=0.004$) and increasing QOL, bringing extra vitality ($p=0.003$) and emotional comfort ($p=0.007$) to the subject. Both US ($p=0.003$) and ESWT therapy ($p=0.001$) effectively reduced pain. In terms of disability, both modalities had similar effects ($p=0.439$). The authors concluded that radial ESWT was significantly more effective than US in reducing pain and providing vitality and emotional comfort to the participant. In terms of disability, US and ESWT therapy had similar effects when associated with kinesitherapy. The researchers stated that additional studies with larger study groups and longer follow-up examinations are needed to confirm these findings, as well as to develop appropriate standardized protocols for these types of subjects. The authors acknowledged that the primary drawback of this study was the lack of a standard protocol regarding radial ESWT and US therapy in scoliosis. Another drawback was the short-term evaluation of the outcomes considered in the study.

Aguilera-Saez and colleagues (2022) reported the results of a prospective, randomized, controlled trial to evaluate the effect of ESWT as an adjunctive treatment in burn scars. Subjects with burn scars were divided into two groups with 20 participants per group. The control group received standard treatment for burn scars. The ESWT cohort received the standard treatment and treatment of burn scars with ESWT twice per week for 4 weeks. The researchers measured the appearance of scar with the Vancouver Scar Scale (VSS), pruritus and pain with Visual Analog Scale (VAS) before the initial treatment and at 2 weeks and 5 months following the treatment. Both groups demonstrated improvements in all variables through the investigation. However, these improvements were only statistically significant for the VSS at the 6th month for the control group and VSS and VAS pain and pruritus for the ESWT group. Nonetheless the results did not demonstrate statistically significant differences between the ESWT and the control group at either 2 weeks or 5 months after treatment. The authors acknowledged that additional studies are required to accurately assess the potential benefits of ESWT as an adjunctive treatment for burn scars.

Extracorporeal Pulse Activation Therapy (EPAT)

Recently a treatment method referred to as “extracorporeal pulse activation therapy” (also known as “EPAT” or extracorporeal acoustic wave therapy), has been proposed for a wide array of orthopedic maladies. This approach uses low energy ESWT to areas of soft tissue inflammation, which has been proposed to promote tissue healing. At this time, only one peer-reviewed study has been published addressing a musculoskeletal condition (Saxena, 2011). This case series study of 60 subjects investigated the use of EPAT for Achilles tendinopathy. The authors reported that 58 (78.38%) tendons improved by at least 1 year post-treatment, including 75% in the subjects with paratendinosis, 78.26% with proximal tendinosis, and 84.21% with insertional tendinosis. No adverse effects were reported. Further research is warranted to properly evaluate the safety and efficacy of this treatment methodology.

Background/Overview

The plantar fascia is a wide ligament-like structure that covers the bottom of the foot, extending from the heel bone to the base of the toes. This band of thick tissue protects the bottom of the heel bone and acts like a shock absorber for the bottom of the foot. The plantar fascia may become irritated, possibly due to repetitive trauma, causing a condition called plantar fasciitis. It is common in several sub-groups of people, including runners and other athletes, people who have jobs that require a fair amount of walking or standing (especially if it is done on a hard surface), and in some cases it is seen in people who have gained weight, including through pregnancy. Once present, plantar fasciitis can take many months to resolve spontaneously with approximately 75% of individuals recovering after 6 months and up to 98% after 12 months.

Extracorporeal shock wave therapy (ESWT), also known as orthotripsy, uses sonic shock waves (high energy sound pulses) focused upon a target tissue associated with pain, discomfort, and functional orthopedic problems. It is theorized that the shock waves disrupt the target tissue, break up scar tissue, reduce inflammation, and stimulate healing.

ESWT treatment involves a series of shock waves, up to several thousand, focused on a target area within the body. When the shock waves are focused on the part of the body needing treatment, the waves impact on the target area with great power, similar to a strong hammer blow. Local anesthesia is usually used to numb the area undergoing treatment. The strength of the shock wave can be controlled to have maximum effect without disturbing surrounding normal tissues.

Potential complications seen with ESWT have been temporary post-operative pain, nerve irritation and numbness. ESWT has been proposed for the treatment of several conditions, including plantar fasciitis, tennis elbow and tendinitis of the shoulders. These conditions have been associated with significant pain and functional limitations. In many cases, these conditions are resistant to conservative treatments such as rest, anti-inflammatory medications and steroid injections, and thus surgical intervention is indicated. ESWT has been proposed as an alternative to surgical treatment for individuals who have failed prior attempts of conservative therapies.

Low-intensity extracorporeal shockwave therapy (LiESWT) has been proposed for the treatment of erectile dysfunction. The treatment consists of sending low-intensity sound waves through erectile tissue, restoring natural erectile function. The exact method of action has not been established. At this time, the Food and Drug Administration (FDA) has not approved a shockwave device for ED.

Definitions

Bicipital tenosynovitis: Bicipital tendinitis is inflammation, irritation, and swelling of the biceps tendon, which is the fibrous structure that joins the biceps muscle to bone.

Calcified tendinitis of shoulder: A condition where the tendons connecting the shoulder muscles to the skeleton become hardened with

calcium deposits, making shoulder movement difficult and painful.

Chronic lateral epicondylitis (tennis elbow): A form of elbow tendinitis where the tendon on the outside part of the elbow becomes inflamed and painful.

Elbow tendinitis: A condition that causes a tendon in the elbow to become inflamed and painful.

Erectile dysfunction: A condition characterized by the inability to get or keep an erection for sexual intercourse.

Non-union fracture: A condition where a bone fails to heal naturally, leaving a gap.

Orthopedic prosthesis: A device, such as a hip or knee replacement prosthesis, that has been surgically implanted in place of a deteriorating body part.

Peyronie's disease: A condition that causes scar tissue to form in the penis, leading to curvature of the penis and painful erections.

Plantar fasciitis: Inflammation of thick tissue on the bottom of the foot caused by chronic irritation resulting in pain while standing, walking, and running.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

CPT	
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
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified
0102T	Extracorporeal shock wave performed by a physician, requiring anesthesia other than local and involving the lateral humeral epicondyle
0512T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; initial wound
0513T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; each additional wound
0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy
ICD-10 Procedure	
6A930ZZ	Shock wave therapy, musculoskeletal, single
6A931ZZ	Shock wave therapy, musculoskeletal, multiple
ICD-10 Diagnosis	
	All diagnoses

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
	12/28/2023	Updated Coding section with 01/01/2024 CPT changes, added 0864T replacing 55899 NOC.
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, References and Websites for Additional Information sections.
Reviewed	05/12/2022	MPTAC review. Updated Rationale, References and Websites for Additional Information sections.
	12/29/2021	Updated Coding section with 01/01/2022 CPT descriptor changes for 0101T, 0102T, 0512T, 0513T; removed 20999 NOC no longer applicable.
Reviewed	05/13/2021	MPTAC review. Updated Rationale, References, and Websites for Additional Information sections.
Reviewed	05/14/2020	MPTAC review. Updated Rationale, References, and Websites for Additional Information sections.
Revised	06/06/2019	MPTAC review. Added erectile dysfunction, Peyronie's disease and wound repair to the INV/NMN statement. Description/Scope, Rationale, Background, References, Websites and Index sections updated. Updated Coding section; added 0512T, 0513T and 55899 (NOC code).
Reviewed	03/21/2019	MPTAC review. Updated Rationale and References sections.
Reviewed	03/22/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Rationale and References sections.
Reviewed	05/04/2017	MPTAC review. Updated Rationale and References sections.
	01/01/2017	Updated Coding section with 01/01/2017 CPT changes; removed code 0019T deleted 12/31/2016.
Reviewed	05/05/2016	MPTAC review. Updated Rationale and Reference sections. Removed ICD-9 codes from Coding section.
Reviewed	05/07/2015	MPTAC review. Updated Rationale and Reference sections.
Reviewed	05/15/2014	MPTAC review. Updated Rationale and Reference sections.
Reviewed	05/09/2013	MPTAC review. Updated Reference and Index sections.
	01/01/2013	Updated Coding section with 01/01/2013 CPT descriptor change.
Reviewed	05/10/2012	MPTAC review. Updated Reference and Index sections.
Revised	05/19/2011	MPTAC review. Added Extracorporeal Pulse Activation Therapy (EPAT®) to the investigational and not medically necessary statement. Updated Rationale, Reference, and Index sections.
Reviewed	05/13/2010	MPTAC review. Updated Rationale and Reference sections.
Reviewed	05/21/2009	MPTAC review. Updated Rationale and Reference sections.
Reviewed	05/15/2008	MPTAC review. Updated Rationale and Reference sections.
	02/21/2008	The phrase "investigational/not medically necessary" was clarified to read "investigational and not medically necessary." This change was approved at the November 29, 2007 MPTAC meeting.
Reviewed	05/17/2007	MPTAC review. Updated Rationale and Reference sections. Coding updated; removed CPT 0020T and HCPCS G0279, G0280 deleted 12/31/2005.
Reviewed	06/08/2006	MPTAC review. Updated Rationale and Reference sections.
	01/01/2006	Updated Coding section with 01/01/2006 CPT/HCPCS changes
Revised	07/14/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organization	Last Review Date	Document Number	Title
Anthem, Inc.	06/12/2001	SURG.00045	Extracorporeal Shock Wave Therapy for Orthopedic Conditions
WellPoint Health Networks, Inc	12/02/2004	10.07.01	Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

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Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.