Cigna Medical Coverage Policy

Subject: Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds

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Coverage Policy

Under many benefit plans, extracorporeal shock wave lithotripsy (ESWL) for musculoskeletal and orthopedic conditions is specifically excluded. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage.

Even when not otherwise specifically excluded under the plan, Cigna does not cover extracorporeal shock wave therapy (ESWT) or extracorporeal pulse activation therapy (EPAT®) for ANY indication, including but not limited to the treatment of musculoskeletal conditions and soft tissue wounds, because it is considered experimental, investigational or unproven.

General Background

Extracorporeal shock wave therapy (ESWT), also referred to as extracorporeal shock wave lithotripsy (ESWL), is a noninvasive treatment that involves delivery of low- or high-energy shock waves via a device to a specific site within the body. These pressure waves travel through fluid and soft tissue; their effects occur at sites where there is a change in impedance, such as the bone/soft-tissue interface. Low-energy shock waves are applied in a series of treatments and do not typically cause any pain. High-energy shock wave treatments are generally given in one session and usually require some type of anesthesia (National Institute for Clinical Excellence [NICE], 2005). The application of radial shock waves represents an alternative to focused shock wave therapy and allows for broader application (Gerdsmeyer, et al., 2008). The most common use for shock waves has been to break kidney stones into fragments that can then be passed.
ESWT is evolving as a proposed treatment option for a variety of conditions, including musculoskeletal disorders and wounds/soft tissue injuries. The mechanism by which ESWT might relieve pain associated with musculoskeletal conditions is unknown. It is thought to disrupt fibrous tissue with subsequent promotion of revascularization and healing of tissue. It has also been hypothesized that the shock waves may reduce the transmission of pain signals from the sensory nerves and/or stimulate healing (Huang, et al., 2000). On that basis, ESWT has been proposed as an alternative to surgery. While ESWT has been investigated as a treatment for various musculoskeletal conditions such as medial epicondylitis (i.e., golfer’s elbow); calcific tendonitis of the rotator cuff; achilles and patellar tendonitis; avascular necrosis of the femoral head; and nonunion of fracture, ESWT devices are FDA approved for only two indications: plantar fasciitis (i.e., heel pain) and lateral epicondylitis (i.e., tennis elbow).

U.S. Food and Drug Administration (FDA)

A number of ESWT devices are currently approved by the FDA. The OssaTron® lithotripter (HealthTronics, Marietta, GA) is an electrohydraulic, high-energy device, approved for treatment of plantar fasciitis and lateral epicondylitis that have failed conservative treatment after six months. The Epos Ultra high-energy device (Dornier Medical Systems, Germering, Germany), uses electromagnetic energy to generate shock waves and is approved for the treatment of chronic plantar fasciitis. The SONOCUR® Basic (Siemens, Erlangen, Germany), a low-dose electromagnetic delivery system, is approved for the treatment of chronic lateral epicondylitis. More recent FDA-approved devices for the treatment of plantar fasciitis include the Orthospec® (Medispec, Ltd, Germantown, MD) and the Orbasone Pain Relief System (Orthometrix, Inc., White Plains, NY). Both are electrohydraulic devices which utilize the spark gap method to create a shock wave. The EMS Swiss Dolorclast® (Electro Medical Systems [EMS], North Attleboro, MA) was granted premarket approval (PMA) by the FDA on May 8, 2007. Indications for use of this device are chronic proximal plantar fasciitis, in patients age 18 and older, with symptoms for six months or more, and a history of unsuccessful conservative therapy.

Plantar Fasciitis

Plantar fasciitis is an overuse injury resulting in inflammation of the plantar fascia, which connects the heel to the toes. It is a common cause of heel pain in adults. Achilles tendinopathy is also a common cause of posterior heel pain. Symptoms of plantar fasciitis usually start gradually with mild pain at the heel, pain after exercise and pain with standing first thing in the morning. On physical examination, firm pressure will elicit a tender spot over the medial tubercule of the calcaneus. Heel spurs are not necessarily associated with plantar fasciitis; heel spurs may be found in asymptomatic patients. Early treatment generally results in a shorter duration of symptoms. Conservative treatment for plantar fasciitis includes rest, physical therapy, heel cushions, nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, foot orthotics, shoe modifications, night splinting, and casting. Surgery is usually considered only for intractable pain which has not responded to 6–12 months of proper conservative treatment. Surgical interventions can include removal or release of the fascia, and removal of bone spurs.

Literature Review: The safety and effectiveness of ESWT for the treatment of plantar fasciitis have been evaluated in technology assessments, meta-analyses, and randomized controlled trials (RCTs). A number of RCTs (n=45–272) have compared ESWT to placebo for the treatment of plantar fasciitis with conflicting results. A greater reduction in heel pain for patients treated with ESWT has been reported in some studies (Gollwitzer, et al., 2015; Othman and Ragab, 2010; Ibrahim, et al., 2010; Gerdesmeyer, et al., 2008; Kudo, et al., 2006; Malay, et al., 2006; Theodore, et al., 2004; Rompe, et al., 2003), while similar improvement rates for both treatment and placebo groups have been reported in other studies (Radwan, et al., 2012; Haake, et al., 2003; Buchbinder, et al., 2002). An RCT (n=32) by Greve et al. (2009) compared radial shockwave treatment (n=16) and conventional physiotherapy (n=16) for plantar fasciitis and found ESWT to be no more effective than conventional physiotherapy three months after treatment. An RCT (n=149) by Wang et al. (2006) found that patients who received ESWT showed significantly better pain and function scores compared to those who received conservative treatment (p<0.001). In general, these studies have limitations such as small sample sizes and short-term follow-up that limit the generalizability of their results.

A Directory Report published by Hayes reviewed the available literature on focused ESWT for Chronic Plantar Fasciitis. The review included randomized controlled trials (RCTs) (n=17 studies), with studies comparing ESWT to sham treatment (10 RCTs), or to other active treatments (6 RCTs), and one RCT comparing full-dose ESWT to low-dose ESWT. Sample sizes ranged from 54 to 293 patients. Outcome measures in studies were patient-rated pain on visual analog scale (VAS), pain threshold, functional measures, quality of life (QOL), overall treatment success, and complications. Follow-up occurred through five years. Some evidence was found...
suggesting that ESWT may decrease patient-reported pain and increase functional outcomes in the short term for patients with plantar fasciitis, however study results were conflicting. Most of the complications reported were transient and consisted of swelling, bruising, and pain or discomfort associated with treatment. The overall body of evidence evaluating ESWT for plantar fasciitis was described as large in size and moderate in quality. The authors noted that despite some positive findings, placebo-controlled trials did not consistently demonstrate statistically significant differences in outcomes between ESWT and sham treatment. It was concluded that additional controlled, blinded long-term safety data from well-designed trials on ESWT for plantar fasciitis are needed further evaluate the technology (Hayes 2016a).

Another published Hayes Directory Report reviewed the available literature on radial ESWT for chronic plantar fasciitis. The review included RCTs (n=10 studies), with studies comparing radial ESWT to sham treatment (4 RCTs), or to other active treatments (5 RCTs), and one RCT comparing radial ESWT with focused ESWT. Sample sizes ranged from 25 to 252 patients. Outcome measures in studies were patient-rated pain on VAS, pain threshold, functional measures, QOL, overall treatment success, and complications. Follow-up ranged from two months to 24 months. Although some of the moderate-size body of evidence suggested that radial ESWT may decrease patient-reported pain and increase functional outcomes in the short term for patients with plantar fasciitis, results were conflicting. When reported, complications were primarily transient and consisted of swelling, bruising, and pain or discomfort associated with treatment. The overall quality of the evidence was low with a small amount of long-term safety data available. Limitations of the of evidence includes methodological weaknesses of individual studies such as lack of long-term follow-up, confounding due to secondary treatments, and high loss to follow-up. Similar to the findings with focused ESWT for the treatment of plantar fasciitis, it was concluded that additional controlled, blinded long-term studies are needed to assess the safety and effectiveness of radial ESWT (Hayes 2016b).

Yin et al. (2014) performed a systematic review and meta-analysis of randomized placebo or active-treatment controlled trials (n=7 RCTs/550 subjects) to assess the efficacy of ESWT for chronic refractory plantar fasciitis. Studies were eligible for inclusion if they were trials that used only one intervention as a control compared with ESWT. Studies that compared different types of shockwave therapy (e.g., radio shockwave therapy, focus shockwave therapy), lacked reporting of successful treatment standards, or for which outcome measures for heel pain could not be separated from the data were excluded. The primary outcome was success treatment rate assessed 12 weeks after intervention. The treatment intensity of ESWT was divided into two levels: low intensity (energy <0.20mJ/mm²) and high intensity (energy >0.2mJ/mm²). Function was the secondary outcome measured by the Roles and Maudsley score, which is used to evaluate pain in relation to daily activities. Follow-up in studies ranged from three to 12 months. In terms of the overall success rate, for the low-intensity group (n=5 trials), ESWT was found to be more effective than control treatment (p<0.001). For the high-intensity group, the pooled data showed that there was no significant difference in the overall success rate between the ESWT and control groups. For pain relief in the low-intensity group, the pooled data showed that there was a significant difference between the ESWT and control groups (p<0.001). The high-intensity group was found to have superior pain relief relative to the control group in one trial only. In the subgroup analysis of short-term function using the Roles and Maudsley score, only low-intensity ESWT was significantly superior over the control treatment. Adverse event-related outcomes were reported in 2/7 trials. No severe adverse events occurred. Study results in this review indicate that low-intensity ESWT for the treatment of refractory plantar fasciitis may be more effective than sham treatment. However, study limitations of heterogeneity and short-term follow-up make it difficult to draw conclusions regarding efficacy.

Aqil et al. (2013) conducted a meta-analysis of prospective RCTs (n=7 studies/663 subjects) to investigate whether there was a significant difference in the change of pain scores from baseline when treated with ESWT (n=294 subjects) and placebo (n=369 subjects). Inclusion criteria for studies were adult patients who continued to be symptomatic despite a minimum of three months of conservative treatments. At 12-week follow-up, patients who received ESWT had better composite pain scores (p = 0.02), and greater reduction in their VAS pain scores (p<0.001) compared to placebo. There was no significant difference in overall success rate of heel pain improvement between ESWT and placebo (p= 0.10). Limitations of the review include short-term follow-up and inconsistency in the types of shock waves administered in the included trials.

Dizon et al. (2013) conducted a systematic review and meta-analysis of clinical trials (2002-2010) to evaluate the effectiveness of ESWT in treating chronic plantar fasciitis. RCTs (n=11studies1287 patients) were included if they compared ESWT to placebo or standard care. The primary outcome measure of interest was overall pain reduction assessed 12 weeks after intervention. Other primary outcome measures considered were pain during
the first few steps in the morning and during activity. Other pain outcomes such as nocturnal pain and pain at pressure were not included in the meta-analysis because these are not typical characteristics of pain in plantar fasciitis. Compared to placebo control, ESWT was more effective in reducing morning pain (p=0.004). There was no difference between ESWT and control in decreasing overall pain, (p= 0.06), however moderate-intensity ESWT was more effective in decreasing overall and activity pain (p<0.00001). There was no significant difference in the effectiveness of decreasing activity pain (p= 0.07). Both moderate- and high-intensity ESWT were more effective in improving functional outcome (p= 0.0001). The adverse effects that were seen more in ESWT were pain on the calcaneal area and calcaneal erythema. Acknowledged study limitations include the lack of consistency in outcome measures, specified dose intensities, and follow-up (Dizon, et al., 2013).

A technology assessment of RCTs evaluating the safety and efficacy of ESWT for the treatment of chronic plantar fasciitis was performed for the Canadian Agency for Drugs and Technologies in Health (CADTH). Ho (2007) concluded “the lack of convergent findings from these randomized trials of ESWT for plantar fasciitis suggests uncertainty about its effectiveness. The evidence reviewed does not support the use of this technology for this condition” (Ho, 2007).

Thomson et al. (2005) performed a systematic review and meta-analysis to investigate the effectiveness of ESWT and to provide a precise estimate of the likely benefits of this therapy. A total of eleven RCTs met inclusion criteria for review. Conclusions were based on a pooled analysis of six RCTs (n=897). The meta-analysis was statistically significant in favor of ESWT for the treatment of plantar heel pain, but the effect size was very small. A sensitivity analysis including only the four trials of highest quality did not produce evidence of a statistically significant benefit. It was summarized that that this systematic review does not support the use of ESWT for the treatment of plantar heel pain in clinical practice (Thomson, et al., 2005).

A Cochrane review by Crawford and Thomson (2003) found some indirect evidence that patients’ heel pain improves spontaneously. Patients with heel pain in all trial arms improved spontaneously, regardless of their treatment allocation, demonstrating that the condition is self-limiting in some patients. ESWT was evaluated in five RCTs using different doses, with no consensus reached regarding variation of range of energy (i.e., high versus low), number of pulses, or number of treatment sessions. The results of the meta-analysis found the effectiveness of ESWT for plantar fasciitis unclear.

Ogden et al. (2002) conducted a meta-analysis of eight prospective RCTs evaluating the effectiveness of ESWT for plantar fasciitis (n=840). Treatment success was variably defined as complete or substantial relief of pre-procedure symptoms, activity limitations, or both. Success rates for five studies using low-energy shock waves ranged from 58–88% (Rompe, et al., 1996; Rompe, et al., 1997; Krischek, et al., 1998; Dahmen, et al., 1995; Buch, et al., 2000). For the three studies that utilized high-energy shock waves, the success rates ranged from 81–87% (Ogden, et al., 2001; Chen, et al., 2001; Wang, et al., 2000).

Professional Societies/Organizations: According to a practice guideline from the American College of Foot and Ankle Surgeons (ACFAS), ESWT may be considered as an alternative to traditional surgical approaches for recalcitrant plantar heel pain (Thomas, et al., 2010).

In a joint policy statement, the American Podiatric Medical Association (APMA) and the ACFAS state that ESWT is one of the many procedures used to treat plantar fasciitis. In addition to the clinical trials used for FDA approval of the Ossatron and Dornier Epos Ultra devices, the societies presented a review of seven studies in their document. Despite the limited evidence from relatively small studies, few randomized trials, and conflicting results identified in the literature, the APMA/ACFAS concluded that “ESWT appears to be an efficacious, FDA-approved, non-surgical option in the treatment of chronic proximal plantar fasciitis” (APMA/ACFAS, 2003).

Lateral Epicondylitis
Lateral epicondylitis is caused by repetitive motion that exerts stress on the grasping muscles of the forearm, which originate at the lateral epicondyle of the elbow. Conservative treatment involves rest, ice, stretching, strengthening, avoiding activity that hurts, and, as healing occurs, strengthening exercises. While the majority of cases of fasciitis, tendonitis and epicondylitis resolve spontaneously with rest and discontinuation of the provoking activity over time, surgical treatment may be indicated for patients who fail conservative treatment.

Literature Review: A number of RCTs (n=56–114) have evaluated the safety and effectiveness of ESWT versus sham for the treatment of lateral epicondylitis. These studies have been limited by short-term follow-up of
6–12 months, and have yielded conflicting results. Some studies have demonstrated significant improvement of pain and/or function for patients in the treatment group (Pettrone and McCall, 2005; Rompe, et al., 2004). Other study results have indicated that ESWT for tennis elbow was no better than placebo (Staples, et al., 2008; Radwan, et al., 2008; Melikyan, et al., 2003).

Vulpiani et al. (2015) conducted a single-blinded RCT (n=80) comparing the effectiveness of ESWT (n=40) to cryoultrasound (n=40) in patients with chronic lateral epicondylitis. Inclusion criteria were adults 18 to 75 years old, diagnosis of chronic lateral epicondylitis within at least three months, intensity of pain ≥ five on the Visual Analogue Scale (VAS) and failure of previous conservative treatments. Criteria for exclusion included previous treatment with cryoultrasound, acute infection, and signs of elbow laxity or instability and neoplastic disease. The primary outcome was a difference of two points in pain recorded on the VAS during the Cozen test between the ESWT group and the cryoultrasound group. The secondary outcome was the number of patients who achieved at least 50% satisfactory results at three, six and 12 months of follow-up. Significant differences between groups for the VAS score were noted at six months (p<0.001) and 12 months (p<0.001) in favor of ESWT group. The satisfaction rate required at 50% was only achieved in the ESWT group in the follow-up at six (62.5%) and 12 (70.0%) months. Pain at the limit of tolerability was reported by all ESWT patients. No side effects or complications were reported by patients receiving ultrasound. Acknowledged limitations of this study include the lack of a placebo group to demonstrate the natural course of the condition and absence of hand grip strength and finger pinch analysis. Additional data are needed to confirm study results.

**Systematic Reviews/Meta-analyses:** Buchbinder et al. (2006) conducted a systematic review to determine the efficacy and safety of ESWT for lateral elbow pain. A total of nine placebo-controlled trials (n=1006) and one trial of ESWT versus steroid injection (n=93) were included. The nine placebo-controlled trials reported conflicting results. Minimal adverse effects of ESWT were reported. It was concluded that ESWT provides little or no benefit in terms of pain and function in lateral elbow pain. Evidence based on one trial suggested that steroid injection may be more effective than ESWT.

In a systematic review, Stasinopoulos and Johnson (2005) evaluated evidence on the effectiveness of ESWT for the management of tennis elbow. The analysis included seven eligible RCTs, all of which had satisfactory methodology but yielded conflicting results. Overall, the quality of studies included in the review was deemed satisfactory, but there were methodological limitations. Many of the studies failed to provide adequate long-term follow-up, blinding, and power calculations. Another deficit was the lack of standardized outcome measures. The reviewers concluded that further research with well-designed RCTs is needed to establish the absolute and relative effectiveness of ESWT in the management of tennis elbow.

Bisset et al. (2005) conducted a systematic review and meta-analysis of the literature on the effectiveness of physical interventions for lateral epicondylalgia (i.e., tennis elbow). There was a lack of evidence found for the long-term benefit of physical interventions in general. Of the eight ESWT studies identified, two met the level of quality needed for inclusion in this analysis. The pooled data from these studies indicated that there was no added benefit over that of placebo for the treatment of tennis elbow (Bisset, et al., 2005).

Buchbinder et al. (2005) conducted a Cochrane review of nine placebo-controlled trials involving 1006 patients and meta-analyses of up to three trials. It was concluded that ESWT has minimal benefits compared to placebo for lateral elbow pain (Buchbinder, et al., 2005).

**Tendonitis of the Shoulder**

In tendonitis of the shoulder, the rotator cuff and/or biceps tendon become inflamed, usually as a result of repetitive activities that involve use of the arm in an overhead position. The injury may vary from mild inflammation to involvement of most of the rotator cuff. As the rotator cuff tendon becomes inflamed and thickened, it may get trapped under the acromion, causing pain and possibly restricted range of motion (ROM). The condition is usually self-limiting. Medical treatment includes rest, ice, and anti-inflammatory medications. Steroid injections are also a treatment option. Surgical intervention is considered if there is no improvement after 6–12 months of optimal medical management.

**Literature Review:** The evidence evaluating the safety and effectiveness of ESWT for tendonitis of the shoulder consists of controlled studies (n=43–144), both randomized and nonrandomized, in addition to technology assessments and systematic reviews. Clinical success has been reported in 60%–80% of patients with disintegration rates of the calcific deposit after ESWT varying from 47%–77% (Hsu, et al., 2008; Mouzopoulos,
et al., 2007). Some studies have compared different energy levels of ESWT (Ioppolo et al., 2012; Peters et al., 2004; Pleiner et al., 2004; Gerdesmeyer et al., 2003). In general, study results have suggested that high-energy ESWT is more effective than low energy ESWT for calcific tendonitis of the shoulder. These studies are limited by short-term follow-up of 6–12 months. In addition, optimal treatment parameters have not been established, and patient selection criteria have not been adequately defined.

Bannuru et al. (2014) conducted a systematic review (n=28 RCTs/1307 subjects) of the evidence to assess the efficacy of ESWT in patients with calcific (n=1134) and non-calcific tendinitis (n=173). Of the 28 RCTs, 20 compared different ESWT energy levels to placebo and eight compared ESWT to other treatments. The quality of trials was reported to be variable and generally low, with numerous sources of bias and heterogeneity (e.g., diverse ESWT regimen/devices), precluding meta-analysis. RCTs were included that studied treatment of calcific or non-calcific tendonitis of the shoulder and compared different energy levels of ESWT or compared ESWT to placebo or other treatments. Nonrandomized comparative studies, single-cohort studies, and case reports were excluded. The outcome measures included of pain, function and calcification resolution which was evaluated only in calcific tendonitis trials. High-energy ESWT was found to be statistically significantly better than placebo for both pain and function. The results for low-energy ESWT favored ESWT for function, while results for pain were inconclusive. The reduction in calcification was significantly greater after high-energy ESWT than after placebo treatment; results for low-energy ESWT were inconclusive. Evidence suggesting a benefit of ESWT for non-calcific tendonitis was also inconclusive. Adverse effects of ESWT were reported to be dose-dependent and generally limited to a temporary increase in pain and local reactions, such as swelling, redness, or small hematomas. Limitations were heterogeneity and size of the included trials. Larger controlled randomized trials as well as standardization of energy levels and treatment protocol are needed to further define the role of ESWT for treating calcific tendinitis of the shoulder.

Ioppolo et al. (2013) conducted a systematic review (n=6 RCTs/460 subjects) to evaluate the effectiveness of ESWT for improving function and reducing pain in patients with calcific tendinitis of the shoulder, and to determine the rate of disappearance of calcifications after therapy. Studies were included that compared ESWT with placebo or no treatment and if participants were adults >18 years of age with shoulder pain or tenderness from calcific tendonitis in patients with type I or II calcification. Exclusion criteria for subjects were history of significant trauma or systemic inflammatory conditions (e.g., rheumatoid arthritis), postoperative shoulder pain, or rotator cuff tear. Of the six RCTs, two were determined to be of methodologically high-quality. Outcome measures were clinical improvement evaluated by shoulder functional scales, and resorption of calcific deposits defined through radiographic examinations. The reduction of pain was found to be clinically significant at six months after treatment. Meta-analysis of studies evaluated the radiologic rate of resorption of calcific deposits at six months of follow-up found ESWT to be superior to no treatment or placebo for partial and total resorption. Reported results indicate that ESWT may be effective in reducing pain and facilitating the resorption of calcium deposits. However these results are limited by the low quality and short-term follow-up of studies and lack of comparison to proven therapies.

Lee et al. (2011) performed a systematic review of RCTs (n=9 studies) examining the midterm effectiveness of ESWT for calcified rotator cuff tendinitis. The review found consistent evidence of midterm effectiveness of ESWT in reducing pain and improving shoulder function. However it was determined that the different outcome measures used and inadequate reporting details in the included studies did not permit a quantitative synthesis of the effectiveness of this treatment. A lack of follow up period beyond one year in the studies was also a limitation and did not allow for conclusions to be made on the longer term effectiveness of ESWT (Lee et al., 2011).

A technology assessment of RCTs evaluating the safety and efficacy of ESWT for the treatment of chronic rotator cuff tendinitis was performed for the Canadian Agency for Drugs and Technologies in Health (CADTH). Ho (2007) found some evidence to support the use of high-energy ESWT for chronic calcific rotator cuff tendinitis. However, it was stated that more high-quality RCTs with larger sample sizes are required to provide more convincing evidence.

Harniman et al. (2004) performed a systematic review to assess the effectiveness of ESWT for the treatment of calcific and noncalcific tendonitis of the rotator cuff. The analysis included five RCTs and 11 nonrandomized trials. The authors 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. Common limitations of the studies included small sample size, lack of randomization and blinding, treatment provider bias, and outcome
measures. It was concluded that high-quality RCTs are needed with larger sample sizes, better randomization and blinding, and better outcome measures.

Professional Societies/Organizations: A position paper by the Ohio Bureau of Workers’ Compensation (BWC) assessed the literature on the use of ESWT for musculoskeletal conditions. The report concluded that studies of ESWT have not shown consistent results or efficacy in the treatment of plantar fasciitis, epicondylitis, and noncalcific tendonitis of the shoulder. Therefore, ESWT is investigational for these indications. Although the use of ESWT in the treatment of calcific tendonitis of the shoulder shows preliminary good results, replication of the results in additional studies would be beneficial. Likewise, additional studies describing beneficial outcomes in the treatment of nonunion of fractures would be valuable (Ohio BWC, 2005).

An assessment of ESWT for musculoskeletal disorders (i.e., plantar fasciitis, lateral epicondylitis, tendonitis of the shoulder, nonunion and delayed union fractures), 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.

Wounds
ESWT has been proposed as a treatment for delayed/non-healing or chronic wounds. The mechanism by which ESWT may provide a therapeutic effect in wounds remains unclear. Potential mechanisms include durable and functional neovascularization and the reduction of pro-inflammatory effects that inhibit wound healing. ESWT is being investigated as a modality to accelerate tissue repair and regeneration in various wounds such as decubitus ulcers, burns and diabetic foot ulcers.

Literature Review: ESWT application for wound healing has been studied in randomized controlled trials and case series. A systematic review (n=5 studies) performed by Butterworth et al. (2015) examined the effectiveness of ESWT for the treatment of lower limb ulceration. Studied included RCTs (n=3 studies/177 patients), one quasi-experimental study (n=40 patients) and one case series (n-31 patients). The majority of wounds assessed were associated with diabetes. The primary outcome was wound improvement or healing. Treatment comparators included standard care and hyperbaric oxygen. Rates of wound healing ranged from 31% - 57%, with two RCTs reporting statistical significance in favor of ESWT. However ESWT protocol varied in studies resulting in study heterogeneity and making comparison difficult. It was noted external validity of studies was poor, making it difficult to generalize study findings (Butterworth et al., 2015).

Ottomann et al. (2012) conducted an RCT (n=44) of patients with acute second-degree burns who were assigned to receive standard therapy of debridement/topical antiseptic with (n=22), or without (n=22) ESWT. Randomization sequence was computer-generated, and patients were blinded to treatment allocation. The primary endpoint was time to complete burn wound epithelialization. Mean time to complete (≥95%) epithelialization for patients that did and did not undergo ESWT was 9.6 ± 1.7 and 12.5 ± 2.2 days, respectively (p< 0.0005).

A case series (n=258) by Wolff et al, (2011) evaluated the possible effects of comorbidities and different wound etiologies on the success of ESWT treatment for of chronic soft tissue wounds were investigated. The median follow-up was 31.8 months. Wound closure occurred in 191 patients (74.03%) by a median of two treatment sessions. No wound reappeared at the same location. Pooled comorbidities and wound etiologies were not found to have a significant influence on the success of ESWT. Study conclusions are limited by the lack of a control group and relatively short-term follow-up.

Moretti et al. (2009) conducted an RCT (n=30) of patients with neuropathic diabetic foot ulcers treated with standard care and ESWT or standard care alone. The healing of the ulcers was evaluated over 20 weeks by the rate of re-epithelization. After 20 weeks of treatment, 53.33% of the ESWT-treated patients had complete wound closure compared with 33.33% of the control patients, and the healing times were 60.8 and 82.2 days, respectively (p<0.001). Significant differences in the index of the re-epithelization were observed between the two groups (p<0.001).

A prospective case series (n=208) by Schaden et al. (2007) evaluated patients with nonhealing acute and chronic soft-tissue wounds whose treatment consisted of debridement, ESWT, and moist dressings. Of the 176 patients completing the study, 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. Age
(p=0.01), wound size ≤ 10 cm(2) (p=0.01), and duration ≤ one month (p< 0.001) were found to be independent predictors of complete healing. Study limitations include lack of a comparison to a control group and short-term follow-up.

Although initial results from several RCTs and case series suggest that ESWT may promote wound healing, well-designed RCTs with larger patient populations and long-term follow-up are needed to support this wound treatment modality.

**Miscellaneous Indications**

ESWT has been proposed for other conditions, including delayed or nonunion fractures and osteonecrosis of the femoral head, low back pain, muscle spasticity, and patellar tendinopathy. ESWT for these indications has been evaluated in few controlled and uncontrolled studies with small patient populations ranging from 15-56 (Vidal, et al., 2011; Chen, et al., 2009; Wang, et al., 2007, Taunton, et al., 2003) and presented in systematic reviews.

A systematic review (n=4 RCTs/252 patients) by Seco et al. (2011) evaluated the evidence on the safety and effectiveness of ultrasound and shock wave to treat low back pain. It was summarized that the available evidence does not support the effectiveness of ultrasound or shock wave for treating LBP. High-quality RCTs are needed to assess their efficacy versus appropriate sham procedures, and their effectiveness compared to other procedures shown to be effective for LBP (Seco, et al., 2011).

Zelle et al. (2010) performed a systematic review (n=11 studies/924 patients) of the literature for the use of ESWT in the treatment of fractures and delayed unions/nonunions. Studies were primarily case series (n=10) with one RCT. The overall union rate in patients with delayed union/nonunion was 76% (95% confidence interval 73%–79%) and ranged from 41% to 85%. Acknowledged limitations of the review included the lack of higher level evidence and lack of comparative data. It was noted that the natural history of these lesions remains unclear, and it may be assumed that some delayed unions may have healed using other non-operative treatment approaches.

One RCT (n=126) by Cacchio et al. (2009) compared ESWT to surgery for the treatment of long bone non-unions. At 24 months of follow-up, there were no differences found in clinical outcomes.

Alves et al. (2009) conducted a systematic review (n=5 studies) of the evidence examining the use of ESWT for osteonecrosis of the femoral head. The studies included two RCTs, an open label study, one comparative prospective study, and one case report. The lack of well-designed studies was noted, although “the non-controlled studies appeared to demonstrate some favorable result” (Alves, et al., 2009).

There is insufficient evidence to draw conclusions regarding the use of ESWT for the treatment of the outlined conditions.

**Extracorporeal Pulse Activation Therapy (EPAT®)**

More recently a variation of ESWT, referred to as EPAT and also known as extracorporeal acoustic wave therapy, has been proposed for orthopedic conditions and soft tissue inflammation. EPAT is described as low-energy pulse-activated shockwave that may propose tissue healing.

**U.S. Food and Drug Administration (FDA):** The D-Actor Vibration Massager System (Storz Medical AG, Tagerwil, Switzerland) was granted marketing approval by the FDA via the 510(k) process on June 27, 2008. The D-Actor 200 is described as “a vibrating percussion massage system that operates by compressed air to perform pulse activation therapy on target muscles and tissues.” The device is intended to be used for the temporary increase in local blood circulation to relieve minor muscle aches and pains (FDA, 2008).

**Literature Review:** Very limited data exists in the published peer-reviewed literature that is specific to the safety and effectiveness of EPAT. A case series (n=60) by Saxena et al. (2011) examined the use of EPAT for achilles tendinopathy and reported an overall pain improvement rate of 78% at one year follow-up.

There is insufficient evidence to support the use of EPAT for the treatment of any orthopedic condition. Evidence in the form of randomized controlled studies with long-term follow-up is needed to determine safety and efficacy of this type of shockwave therapy.
Use Outside of the US
The Australia and New Zealand Horizon Scanning Network’s (ANZHSN) scanning program is a collaborative Commonwealth and State initiative guided by the Health Policy Advisory Committee on Technology (HealthPACT), which provides jurisdictions with evidence-based advice on emerging technologies. A 2004 ANZHSN Horizon Scanning prioritizing summary on ESWT for chronic rotator cuff calcific tendonitis determined the level of use in Australia to be limited, stating that the technology is available through sports medicine clinics (ANZHSN, 2004).

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating therapeutic goods including medicines, medical devices, blood and blood products. Any product for which therapeutic claims are made must be listed, registered or included in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia. The following devices are included in the ARTG listing:

1. Orthopaedic extracorporeal shock wave therapy system (Dornier MedTech GmbH, Wessling, Germany) as of September 9, 2010; intended use is for treating musculoskeletal disorders (e.g., tendinopathies and soft tissue pain near bones, plantar fasciitis, epicondylopathy) and other related muscle pain syndromes
2. Electromechanical orthopaedic extracorporeal shock wave therapy system (Richard Wolf GmbH, Knittlingen, Germany) as of February 11, 2012; intended use is for the elimination of chronic pain using focused, extracorporeal shock wave therapy and trigger point shock wave therapy

The University of New South Wales (UNSW) (2013) developed guidelines for the clinical management of rotator cuff syndrome in the workplace. The stated primary objective of these guidelines is to provide evidence-based recommendations to improve clinical outcomes for workers, employers and health care providers. According to the UNSW guidelines, when non-surgical measures fail and pain continues to significantly restrict routine activities, needle aspiration, surgical removal or ESWT may be indicated. Most of the evidence supporting ESWT for calcific tendonitis originates in Europe where there is widespread use of this technique. The UNSW further states that in Australia, ESWT is only available in a limited number of sports medicine clinics (Hopman, et al., 2013).

The National Institute for Health and Clinical Excellence (NICE) issued a guidance on the use of ESWT for refractory plantar fasciitis. According to NICE, a review of the evidence raises no major safety concerns; however, current evidence on the efficacy of ESWT for this indication is inconsistent. Therefore, the procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE, 2009b; 2012b).

A NICE guidance on the use of ESWT for refractory tennis elbow states that the evidence on ESWT for refractory tennis elbow raises no major safety concerns; however, current evidence on its efficacy is inconsistent. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE, 2009d; 2012d). According to the NICE guidance on the use ESWT for calcific tendonitis of the shoulder, current evidence on the safety and efficacy appears adequate to support the use of the procedure provided that normal arrangements are in place for consent, audit, and clinical governance (NICE, 2003; 2012c).

Summary
Extracorporeal shock wave therapy (ESWT) has been studied in a variety of applications including musculoskeletal conditions and wound healing. Some unanswered questions remain, and the data are inconclusive as to the effectiveness of ESWT for the treatment of musculoskeletal conditions. The medical literature suggests that the effectiveness of ESWT for the two U.S. Food and Drug Administration (FDA)-approved conditions (i.e., lateral elbow pain and plantar fasciitis) is unclear, as trials have yielded conflicting information. A strong placebo effect has been demonstrated for this technology (Buchbinder, 2002). There is insufficient evidence in the peer-reviewed scientific literature to support the use of ESWT, including extracorporeal pulse activation therapy (EPAT®), for any musculoskeletal indication, (e.g., plantar fasciitis, Achilles tendinopathy, lateral epicondylitis, tenosynovitis of the shoulder, delayed or nonunion fractures, and osteonecrosis of the femoral head.)
Available evidence in the published peer-reviewed medical literature evaluating the safety and effectiveness of ESWT for wound healing is of inadequate quantity and quality to support its use for this indication. Likewise evidence from well-designed clinical trials on the use of ESWT for conditions such as low back pain and muscle spasticity is lacking.

Although ESWT may be a relatively safe procedure, the overall efficacy of this treatment modality remains unproven at this time.

**Coding/Billing Information**

**Note:**
1. This list of codes may not be all-inclusive.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Experimental/Investigational/Unproven/Not Covered:**

<table>
<thead>
<tr>
<th>CPT* Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20999</td>
<td>Unlisted procedure, musculoskeletal system, general</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>
<tr>
<td>0019T</td>
<td>Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy (Code deleted 12/31/2016)</td>
</tr>
<tr>
<td>0101T</td>
<td>Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy</td>
</tr>
<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>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>
</tbody>
</table>


**References**


36. Huisstede BM, Gebremariam L, van der Sande R, Hay EM, Koes BW. Evidence for effectiveness of Extracorporeal Shock-Wave Therapy (ESWT) to treat calcific and non-calcific rotator cuff tendinosis--a


