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 tubercle 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 (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.

Technology Assessments: 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).
The ECRI Institute issued an evidence report on the use of ESWT for the treatment of plantar fasciitis in 2006. The evidence included RCTs (n=13) and case series (n=7) with a total of 2,233 patients. Only four trials that used a single high-energy treatment met inclusion criteria for the analysis. Study results indicated that patients treated with a single session of high energy ESWT had less pain on the first few steps in the morning than patients given a sham treatment. No evidence-based conclusion could be reached by ECRI as to whether patients treated with a course of low or medium energy ESWT had less, more, or the same amount of pain than patients given a sham treatment. It was summarized that ESWT is a safe procedure that may provide some relief from the pain of chronic plantar fasciitis; however, the degree of pain relief may not be clinically significant. An update to this evidence report issued in 2011 stated that these conclusions remain valid (ECRI, 2011).

**Systematic Reviews/Meta-analyses:** 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 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).

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. The authors stated 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).

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% (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.

Lee et al. (2011) performed a systematic review of RCTs (n=9 studies) examining the midterm effectiveness of ESWT for calcified rotator cuff tendonitis. 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).

An RCT (n=47) by Hsu et al. (2008) found post-treatment improvement of pain and function to be statistically significant for the ESWT group (p < 0.001), but not for the control group (p > 0.05).

A technology assessment of RCTs evaluating the safety and efficacy of ESWT for the treatment of chronic rotator cuff tendonitis 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 tendonitis. 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. 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 \((\geq 95\%)\) epithelialization for patients that did and did not undergo ESWT was \(9.6 \pm 1.7\) and \(12.5 \pm 2.2\) 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 \(\leq 10 \text{ cm}^2\) \((p=0.01)\), and duration \(\leq\) 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, Tagerwilen, 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 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).

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). 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, 2003b).

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, tendonitis 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>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</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>
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References


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