



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions

Effective Date 12/15/2008
Next Review Date..... 12/15/2009
Coverage Policy Number0004

Table of Contents

Coverage Policy	1
General Background	1
Coding/Billing Information	7
References	8
Policy History.....	13

Hyperlink to Related Coverage Policies

Lower Limb Orthoses
Plantar Fasciitis Treatments

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2008 CIGNA

Coverage Policy

CIGNA does not cover extracorporeal shock wave therapy (ESWT) for the treatment of any musculoskeletal condition, because it is considered experimental, investigational or unproven.

General Background

Extracorporeal shock wave therapy (ESWT) 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 most common use for shock waves is to break kidney stones into fragments that can then be passed.

ESWT is evolving as a proposed treatment option for a variety of musculoskeletal conditions, including 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. 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, 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. Symptoms 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. Risk factors for plantar fasciitis may include obesity, age, being female, limited dorsiflexion of the ankle joint, prolonged weight bearing and an increase in the amount of walking or running. 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: Chow and Cheing (2007) conducted an RCT (n=57) to compare the effectiveness of different energy densities of ESWT for managing chronic heel pain. Patients were randomized into one of three groups receiving either a fixed energy density (n=19), a maximum tolerable energy density (n=19), or control treatment once a week for three weeks (n=19). Pain on palpation, pain on tension, maximum tolerable walking/standing duration and Foot Function Index were assessed before treatment in each treatment session and at the three-week follow-up. At this follow-up, the maximum tolerable energy density group experienced a 66% cumulative reduction in pain from tension, a 65% reduction on palpation and a 112% cumulative increase in maximum tolerable walking/standing duration. The fixed energy density group experienced a 45% cumulative reduction in pain from tension, a 32% reduction in pain on palpation, and a 45% increase in walking/standing tolerance. The maximum tolerable energy density group also showed a significantly greater reduction in Foot Function Index scores than the other two groups. Therapeutic effects were maintained up to the three-week follow-up period. The control group had no significant changes in any outcome measures. A total of eight patients withdrew from the study. The authors note that because of the small sample size and short-term follow-up of this study, the long-term effects of ESWT should be evaluated in subsequent studies (Chow and Cheing, 2007).

Wang et al. (2006) conducted a prospective RCT of 149 patients (168 heels) with chronic plantar fasciitis. In the shock wave group (n=79), patients received high-energy ESWT to the affected heel in a single session. Patients in the control group (n=70) received conservative treatment consisting of nonsteroidal anti-inflammatory drugs, orthotics, physical therapy, an exercise program, and/or a local cortisone injection. Follow-up occurred at 34–64 months for the control group and 60–72 months for the treatment group, with a 100-point scoring system, including 70 points for pain and 30 points for function. The clinical outcomes were rated as excellent, good, fair, or poor. After treatment, the shock wave group showed significantly better pain and function scores compared to the control group (p< 0.001). The recurrence rate was reported to be 11% (9/81 heels) for the shock wave group versus 55% (43/78 heels) for the control group (p<0.001). No complications or device-related problems were reported. The authors concluded that ESWT is safe and effective for patients with plantar fasciitis, with good

long-term results. Acknowledged weaknesses of the study include lack of treatment standardization in the control group and the lack of a sham procedure in the study design (Wang, et al., 2006).

In a prospective, double-blind RCT, Malay and colleagues (2006) compared the outcomes of patients treated with ESWT (n=115) versus those treated with placebo (n=57) for proximal plantar fasciitis. The primary outcomes were objective and subjective assessments of heel pain obtained at three months of follow-up. Patients were followed up to one year to identify any adverse events. On the visual analog scale (VAS), the blind assessor's objective assessment of heel pain displayed a mean reduction of 2.51 in the shock wave group and 1.57 in the placebo group, a difference which was statistically significant (p=0.045). The participant's self-assessment of heel pain on the VAS showed a mean reduction of 3.39 in the shock wave group and 1.78 in the placebo group (p<0.001). No serious adverse events were observed. It was concluded that ESWT was both efficacious and safe for participants with chronic proximal plantar fasciitis that had been unresponsive to conservative treatment. Study limitations considered by the investigators include short-term follow-up and decreased generalizability of findings caused by the exclusion of patients with bilateral proximal plantar fasciitis (Malay, et al., 2006).

Kudo et al. (2006) conducted a multicenter, randomized, placebo-controlled, double-blind, clinical study to determine whether high-energy ESWT can safely and effectively relieve the pain associated with chronic plantar fasciitis compared to placebo treatment. The primary outcome was pain during the first few minutes of walking, measured by a VAS. Clinical success was defined as a greater than 60% improvement from baseline. A statistically significant difference was found in the change from baseline to three months in the VAS scores of the treated (n=58) versus the placebo group (n=56) (p=0.0124). There was also a statistically significant difference between treatment groups in the number of patients whose changes in VAS scores met the study definition of success at both six weeks and three months after treatment (p=0.0099). In the opinion of the authors, the results of this study support the safety and efficacy of this ESWT device when used to treat recalcitrant plantar fasciitis.

A Blue Cross Blue Shield Association technology assessment evaluated whether ESWT improves health outcomes for patients with plantar fasciitis that is unresponsive to conservative measures. Evidence was reviewed from five double-blind RCTs reporting on a total of 878 patients (Healthtronics Surgical Services, Inc., 2002/Ogden, et al., 2001; Dornier Medical Systems, Inc., 2002/Theodore, et al., 2004; Buchbinder, et al., 2002; Haake, et al., 2002; Rompe, et al., 2003). High-energy ESWT was used in two of these trials. Improvement in morning pain and increased activity were the most common outcome measures. The evidence was found to be insufficient to permit a conclusion on the health outcome effects of ESWT for plantar fasciitis. Where reported, improvement in morning pain was not accompanied by a significant difference in quality-of-life measurement or use of pain medication. It was concluded that ESWT for chronic plantar fasciitis has not been demonstrated to improve health outcomes in the investigational setting (Blue Cross Blue Shield Association, 2005).

A Hayes review of the evidence evaluated a total of 11 randomized trials grouped as low energy or high energy. Treatment with ESWT resulted in symptom improvement at three or six months in all studies. However, placebo-controlled trials did not consistently show statistically significant differences in outcomes between ESWT and sham treatments. Even where differences were statistically significant, the clinical significance could not be evaluated because there was a lack of consensus on what constitutes a clinically meaningful difference in short-term results. The report stated that many studies had methodological weaknesses, some of which might hide or inflate a treatment effect of ESWT. Although the studies of high-energy ESWT appeared to have more positive and more robust results than the studies of low-energy ESWT, none of the studies provided a direct comparison of the effectiveness of one versus the other. Therefore, it is unclear whether differences in study results can be attributed to high or low energy level or to other factors. The review concluded that "there is some evidence that ESWT can provide a moderate degree of pain relief in selected patients with chronic plantar fasciitis who have failed appropriate conservative therapy, with relatively few adverse effects. However, optimal treatment parameters have not been established, patient selection criteria have not been adequately defined, and there is a lack of information regarding the durability of treatment effect or any long-term adverse effects of ESWT" (Hayes, 2005).

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).

The Institute for Clinical Systems Improvement (ICSI) conducted a technology review of ESWT for plantar fasciitis and concluded that, although it is a safe, nonsurgical procedure, the current scientific evidence does not permit a conclusion to be reached regarding the efficacy of ESWT for plantar fasciitis (ICSI, 2004).

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 (Rompe, 1996a; Rompe, 1996b; Krischek, 1998; Ogden, 2000; Buchbinder, 2002). The results of the meta-analysis found the effectiveness of ESWT for plantar fasciitis unclear.

In a randomized, blinded, multicenter trial with parallel group design, Haake et al. (2003) evaluated the effectiveness of ESWT (n=135) compared to placebo (n=137) for the treatment of chronic plantar fasciitis. The primary outcome measure was the success rate 12 weeks after intervention based on the Roles and Maudsley score. Secondary outcome measures included subjective pain ratings and walking ability up to a year after the last intervention. The primary end point could be assessed in 94% (n=256) of patients. Statistically similar success rates for improvement were found in treated and placebo groups at 12-week and one-year follow-up.

A prospective RCT conducted by Rompe et al. (2003) compared applications of low-energy ESWT to sham treatment of chronic plantar fasciitis in long-distance runners. Athletes with intractable plantar heel pain for more than 12 months were assigned to receive either three applications of 2100 impulses of low-energy shock waves (n=22) or sham treatment (n=23). Follow-up examinations were performed at six months and at one year by a blinded observer. At six-month follow-up, the ESWT group had greater improvement on self-assessment of morning pain compared to the placebo group ($p<0.01$). Treatment success was reported to be 60% for the ESWT group and 27% for the placebo group ($p=0.06$). The investigators noted that although study results demonstrated beneficial effects of low-energy ESWT, further study is needed to compare the effectiveness of repeated low-energy versus single high-energy shock wave applications for the treatment of chronic plantar fasciitis (Rompe, et al., 2003).

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; Wang, et al., 2000; Chen, et al., 2001). It was concluded that “the therapeutic application of extracorporeal shock waves is clinically effective for the treatment of chronic proximal plantar fasciitis and that high-energy shock wave impulses appear to be more effective.” This meta-analysis was included in a systematic review done by the National Institute for Clinical Excellence (NICE). The NICE committee noted that there appeared to be some overlap in the study populations and that results from control groups were not consistently reported (NICE, 2005).

Buchbinder et al. (2002) conducted a double-blind, randomized, placebo-controlled trial to determine whether ultrasound-guided ESWT reduces pain and improves function in patients with plantar fasciitis. Patients were randomly assigned to receive either ultrasound-guided ESWT (n=81), given weekly for three weeks to a total dose of at least 1000 mJ/mm², or identical placebo (n=85) to a total dose of 6.0 mJ/mm². Outcome measures included morning and activity-related pain measured on a visual analog scale; Maryland Foot Score; walking ability; Short-Form-36 Health Survey (SF-36) score; and Problem Elicitation Technique score, measured at six and 12 weeks after completion of treatment. No statistically significant differences were found between groups for any outcome measures. The results of this short-term RCT suggest that ESWT as applied was no better than placebo for the treatment of plantar fasciitis.

Professional Societies/Organizations: In a joint policy statement, the American Podiatric Medical Association (APMA) and the American College of Foot and Ankle Surgeons (ACFAS) acknowledge 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: Staples et al. (2008) conducted a double-blind, randomized, placebo-controlled trial (n=68) to determine if ultrasound-guided ESWT reduced pain and improved function in patients with lateral epicondylitis in the short term and intermediate term. Patients in the experimental group (n=36) received three treatments of 2000 shockwaves weekly. Those in the placebo group (n=32) received a subtherapeutic dose of 200 shockwaves once per week for three weeks. The mean changes in outcome measures relating to pain and function were collected at follow-up evaluations at six weeks, three months, and six months after completion of the treatment and compared between the two groups. A total of 55 patients were available for six-month follow-up. There were significant improvements in almost all outcome measures for both groups over the six-month follow-up period. No significant differences between the ESWT and placebo groups were found at any of the follow-up points for any of the measured outcomes. The authors noted that “the most likely explanation for improvement in both groups is the self-limiting natural history of the condition whereby most patients with lateral epicondylitis recover in one year” (Staples, et al., 2008).

Radwan et al. (2008) conducted an RCT of 56 patients with tennis elbow of more than six months duration. These patients were randomly assigned to two treatment groups: group 1 (n = 29) received high-energy ESWT without local anesthesia; group 2 (n = 27) underwent percutaneous tenotomy of the common extensor origin. Outcome measures included pain scores and restoration of grip strength. Both groups achieved improvement from the base line at three weeks, six weeks, 12 weeks and 12 months post-intervention. No significant differences between the ESWT and operative groups were found across the different time periods for any measured parameters.

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.

A 2005 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) assessment reviewed six randomized, double-blind, placebo-controlled trials to evaluate the effectiveness of ESWT for lateral epicondylitis deemed unresponsive to conservative measures. The assessment concluded that the available data did not provide strong and consistent evidence that ESWT improves outcomes of chronic lateral epicondylitis (Blue Cross Blue Shield Association TEC, 2005).

A Hayes review of the evidence on the use of ESWT as a treatment for lateral epicondylitis analyzed 10 randomized trials. The selected trials did not utilize a wide enough range of shock wave values to allow for a comparison of high- versus low-energy ESWT. Evidence regarding the efficacy of ESWT for lateral epicondylitis was found to be conflicting. Variations in selection criteria, type of analysis, length of follow-up period, and loss to follow-up hampered interpretation of the studies (Hayes, 2005).

NICE completed a systematic review on the use of ESWT for refractory tendinopathies (i.e., plantar fasciitis and tennis elbow). The review was based on six RCTs and one meta-analysis. In terms of validity and generalizability, the total treatment dose administered varied between studies. Different outcome measures and criteria for defining a successful outcome were used. Also, different methods of anesthesia were used which may have affected outcome. There appeared to be some overlap between the studies, and some patients may

have been included in more than one report. According to the NICE, the current evidence on extracorporeal shock wave therapy for refractory tendinopathies, specifically tennis elbow and plantar fasciitis, suggests that there are no major safety concerns. Evidence on efficacy is conflicting and suggests that the procedure produces little benefit apart from a placebo response in some patients (NICE, 2005).

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. (2002) performed a meta-analysis to determine the effectiveness and safety of ESWT in the treatment of adults with lateral elbow pain. According to the reviewers, the two trials included in the analysis (Rompe, 1996; Haake, 2001) had conflicting results. It was concluded that further trials are needed to clarify the value of ESWT for elbow pain. An update to this Cochrane review, based on a systematic review of nine placebo-controlled trials involving 1006 patients and meta-analyses of up to three trials, 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: Hsu et al. (2008) conducted a prospective RCT to evaluate ESWT for calcific tendinitis of the shoulder in 46 patients. The mean duration of the condition at the time of treatment was 12.3 months. All patients were randomly assigned to either the treatment group (n=33) or the control group (n=13). The 33 patients in the treatment group received two courses of ESWT at the energy density of 0.55 mJ/mm² (1000 impulses). The control group underwent sham treatment (n=13). Outcome measures included pain scores and function evaluated by the 100-point Constant scoring system. Follow-up occurred at six weeks, 12 weeks, six months and one year. Post-treatment improvement of pain and function was found to be statistically significant for the ESWT group ($p < 0.001$), but not for the control group ($p > 0.05$). In the investigators' opinion, "ESWT shows promise for pain relief and functional restoration of calcific tendinitis with negligible complications" (Hsu, et al., 2008). Study results are limited by the small sample size and relatively short-term follow-up.

A Hayes report found some evidence from RCTs that ESWT at sufficiently high levels can provide pain relief and improve shoulder function in some patients with chronic tendonitis of the rotator cuff. The strongest effect was seen in patients with calcific tendonitis who are treated with high-energy ESWT. However, optimal treatment parameters have not been established, and patient selection criteria have not been adequately defined (Hayes, 2005).

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. There was moderate evidence in one underpowered, high-quality study to demonstrate that low-energy ESWT is not effective for treating chronic noncalcific rotator cuff tendonitis. 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.

A 2003 Blue Cross Blue Shield Association TEC assessment of ESWT for musculoskeletal indications, including plantar fasciitis, and both tendonitis of the shoulder and elbow, concluded that the procedure does not meet the TEC criteria. It was determined that the evidence is not sufficient to draw conclusions regarding the health outcome effects of ESWT for any of the indications evaluated nor to conclude whether the technology is as beneficial as alternatives (Blue Cross Blue Shield Association TEC, 2003).

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.

Summary

Extracorporeal shock wave therapy (ESWT) has been studied in various musculoskeletal applications. Some unanswered questions remain, and the data are inconclusive as to the effectiveness of ESWT for the treatment of musculoskeletal conditions. A review of the medical literature shows 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 for any musculoskeletal indication. Therefore, the use of ESWT for the treatment of these indications remains unproven at this time.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
28890	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia
0019T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy
0102T	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving humeral epicondyle

HCPCS Codes	Description
	No specific codes

ICD-9-CM Diagnosis Codes	Description

References

1. Alvarez R. Preliminary results on the safety and efficacy of the OssaTron for treatment of plantar fasciitis. *Foot Ankle Int.* 2002 Mar;23(3):197-203.
2. American Podiatric Medical Association (APMA)/American College of Foot and Ankle Surgeons (ACFAS). APMA and ACFAS Joint Policy Statement on Extracorporeal Shock Wave Therapy. December, 2003. Accessed Nov 7, 2005. Available at URL address: http://www.acfas.org/NR/rdonlyres/17CA33BD-A58B-40CB-9674-1392E7890076/0/ESWT_APMA_ACFASPolicyFinal_12_8_2003.pdf
3. Bisset L, Paungmali A, Vicenzino B, Beller E. A systematic review and meta-analysis of clinical trials on physical interventions for lateral epicondylalgia. *Br J Sports Med.* 2005 Jul;39(7):411-22; discussion 411-22.
4. Blue Cross Blue Shield Association, Technology Evaluation Center. Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Indications. Technology assessment. 2003 Aug. Accessed Nov 4, 2004. Available at URL address: http://www.bcbs.com/tec/Vol18/18_17.pdf
5. Blue Cross Blue Shield Association, Technology Evaluation Center. Extracorporeal Shock Wave Therapy (ESWT) for Chronic Tendinitis of the Elbow (Lateral Epicondylitis). Technology assessment. 2005 Feb. Accessed Oct 27, 2005. Available at URL address: http://www.bcbs.com/tec/Vol19/19_16.pdf
6. Blue Cross Blue Shield Association, Technology Evaluation Center. Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis. Technology assessment. 2005 Mar. Accessed Oct 27, 2005. Available at URL address: http://www.bcbs.com/tec/Vol19/19_18.pdf
7. Buchbinder R, Green S, Barnsley L, Smidt N, Asendelft WJ. Shock wave therapy for lateral elbow pain. *Cochrane Database Syst Rev.* 2002;(1):CD003524.
8. Buchbinder R, Ptaszik GJ, Buchman J, Prabakaran V, Forbes A. Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis: a randomized controlled trial. *JAMA.* 2002 Sep 18;288(11):1364-72.
9. Buchbinder R. Clinical practice. Plantar fasciitis. *N Engl J Med.* 2004 May 20;350(21):2159-66.
10. Buchbinder R, Green S, Youd J, Asendelft W, Barnsley L, Smidt N. Shock wave therapy for lateral elbow pain. *Cochrane Database Syst Rev.* 2005 Oct 19;4:CD003524.
11. Buchbinder R, Green SE, Youd JM, Assendelft WJ, Barnsley L, Smidt N. Systematic review of the efficacy and safety of shock wave therapy for lateral elbow pain. *J Rheumatol.* 2006 Jul;33(7):1351-63.
12. Chow IH, Cheing GL. Comparison of different energy densities of extracorporeal shock wave therapy (ESWT) for the management of chronic heel pain. *Clin Rehabil.* 2007 Feb;21(2):131-41.
13. Chung B, Wiley JP. Extracorporeal shockwave therapy: a review. *Sports Med.* 2002;32(13):851-65.
14. Cole C, Seto C, Gazewood J. Plantar fasciitis: evidence-based review of diagnosis and therapy. *Am Fam Physician.* 2005 Dec 1;72(11):2237-42.
15. Crawford F, Thompson C. Interventions for treating plantar heel pain. *Cochrane Database Syst Rev.* 2003;(3):CD000416.

16. Gerdesmeyer L, Wagenpfeil S, Haake M, Maier M, Loew M, Wortler K, et al. Extracorporeal shock wave therapy for the treatment of chronic calcifying tendonitis of the rotator cuff: a randomized controlled trial. *JAMA*. 2003 Nov 19;290(19):2573-80.
17. Haake M, Buch M, Shoellner C, Goebel F, Vogel M, Mueller I, et al. Extracorporeal shock wave therapy for plantar fasciitis: randomised controlled multicentre trial. *BMJ*. 2003 Jul 12;327(7406):75.
18. Hammer DS, Rupp S, Ensslin S, Kohn D, Seil R. Extracorporeal shock wave therapy in patients with tennis elbow and painful heel. *Arch Orthop Trauma Surg*. 2000;120(5-6):304-7.
19. Hammer DS, Adam F, Kreutz A, Kohn D, Seil R. Extracorporeal shock wave therapy (ESWT) in patients with chronic proximal plantar fasciitis: a 2-year follow-up. *Foot Ankle Int*. 2003 Nov;24(11):823-8.
20. Harniman E, Carette S, Kennedy C, Beaton D. Extracorporeal shock wave therapy for calcific and noncalcific tendonitis of the rotator cuff: a systematic review. *J Hand Ther*. 2004 Apr-Jun;17(2):132-51.
21. Haupt G. Use of extracorporeal shock waves in the treatment of pseudarthrosis, tendonopathy and other orthopedic diseases. *J Urol*. 1997 Jul;158(1):4-11.
22. HAYES Medical Technology Directory™. Extracorporeal Shock Wave Therapy for Chronic Epicondylitis for the Elbow. Lansdale, PA: HAYES, Inc.; ©2005 Winifred S. Hayes, Inc. Originally published 2003 May. Last updated 2005 Aug.
23. HAYES Medical Technology Directory™. Extracorporeal Shock Wave Therapy for Chronic Plantar Fasciitis. Lansdale, PA: HAYES Inc.; ©2005 Winifred S. Hayes, Inc. Originally published 2001 Apr. Last updated 2005 Aug.
24. HAYES Medical Technology Directory™. Extracorporeal Shock Wave Therapy for Tendonitis of the Rotator Cuff. Lansdale PA: HAYES, Inc. ©2005 Winifred S. Hayes, Inc. 2005 Aug.
25. HealthTronics Surgical Services, Inc. OssaTron. Updated 2002. Accessed Nov 5, 2004. Available at URL address: <http://www.healthtronics.com>
26. Ho C. Extracorporeal shock wave treatment for chronic plantar fasciitis (heel pain). *Issues Emerg Health Technol*. 2007 Jan;(96 (part 1)):1-4.
27. Ho C. Extracorporeal shock wave treatment for chronic lateral epicondylitis (tennis elbow). *Issues Emerg Health Technol*. 2007 Jan;(96 (part 2)):1-4.
28. Ho C. Extracorporeal shock wave treatment for chronic rotator cuff tendonitis (shoulder pain). *Issues Emerg Health Technol*. 2007 Jan;(96 (part 3)):1-4.
29. Hsu CJ, Wang DY, Tseng KF, Fong YC, Hsu HC, Jim YF. Extracorporeal shock wave therapy for calcifying tendinitis of the shoulder. *Shoulder Elbow Surg*. 2008 Jan-Feb;17(1):55-9.
30. Huang HH, Qureshi AA, Biundo JJ Jr. Sports and other soft tissue injuries, tendonitis, bursitis, and occupation-related syndromes. *Curr Opin Rheumatol*. 2000 Mar;12(2):150-4.
31. Institute for Clinical Systems Improvement (ICSI), Technology Assessment Committee. Extracorporeal Shock Wave Therapy for Plantar Fasciitis. November, 2004. Accessed Oct 27, 2005. Available at URL address: <http://www.icsi.org/knowledge/detail.asp?catID=107&itemID=1926>
32. Kudo P, Dainty K, Clarfield M, Coughlin L, Lavoie P, Lebrun C. Randomized, placebo-controlled, double-blind clinical trial evaluating the treatment of plantar fasciitis with an extracorporeal shockwave therapy (ESWT) device: a North American confirmatory study. *J Orthop Res*. 2006 Feb;24(2):115-23.

33. Lee GP, Ogden JA, Cross GL. Effect of extracorporeal shock waves on calcaneal bone spurs. *Foot Ankle Int.* 2003 Dec;24(12):927-30.
34. Maier M, Steinborn M, Schmitz C, Koehler A, Feitenhansi A, Durr H, et al. Extracorporeal shock wave application for chronic plantar fasciitis associated with heel spurs: prediction of outcome by magnetic resonance imaging. *J Rheumatol.* 2000 Oct;27(10):2455-62.
35. Malay DS, Pressman MM, Assili A, Kline JT, York S, Buren B, et al. Extracorporeal shockwave therapy versus placebo for the treatment of chronic proximal plantar fasciitis: results of a randomized, placebo-controlled, double-blinded, multicenter intervention trial. *J Foot Ankle Surg.* 2006 Jul-Aug;45(4):196-210.
36. Martini L, Giavaresi G, Fini M, Torricelli P, de Pretto M, Schaden W, et al. Effect of extracorporeal shock wave therapy on osteoblastlike cells. *Clin Orthop Relat Res.* 2003 Aug;(413):269-80.
37. Mouzopoulos G, Stamatakos M, Mouzopoulos D, Tzurbakis M. Extracorporeal shock wave treatment for shoulder calcific tendonitis: a systematic review.. *Skeletal Radiol.* 2007 Sep;36(9):803-11. Epub 2007 Apr 6.
38. National Institute for Clinical Excellence (NICE). Interventional Procedures Programme. Interventional procedures overview of extracorporeal shock wave therapy for refractory tendinopathies (plantar fasciitis and tennis elbow). January 2005. Accessed October 27, 2005. Available at URL address: <http://www.nice.org.uk/pdf/ip/252%20ESWT%20overview%20for%20web.pdf>
39. National Institute for Clinical Excellence (NICE). Interventional Procedures Consultation Document - Extracorporeal shock wave therapy for refractory tendinopathies (plantar fasciitis and tennis elbow). June 2005. Accessed October 27, 2005. Available at URL address: <http://www.nice.org.uk/page.aspx?o=258820>
40. Ogden JA, Alvarez R, Levitt R, Cross G, Marlow M. Shock wave therapy for chronic proximal plantar fasciitis. *Clin Orthop.* 2001 Jun;(387):47-59.
41. Ogden JA, Alvarez RG, Marlow M. Shockwave therapy for chronic proximal plantar fasciitis: a meta-analysis. *Foot Ankle Int.* 2002 Apr;23(4):301-8.
42. Ogden JA, Alvarez RG, Levitt RL, Johnson JE, Marlow ME. Electrohydraulic high-energy shock-wave treatment for chronic plantar fasciitis. *J Bone Joint Surg Am.* 2004 Oct;86-A(10):2216-28.
43. Ohio Bureau of Workers' Compensation (BWC). Position Paper on Use of Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Problems. April 2004. Revised September 2005. Accessed Nov 12, 2006. Available at URL address: <http://www.ohiobwc.com/downloads/blankpdf/PositionShockWaveTherapy.pdf>
44. Park SH, Park JB, Weinstein JN, Loening S. Application of extracorporeal shock wave lithotripter (ECSWL) in orthopedics. I. Foundations and overview. *J Appl Biomater.* 1991 Summer;2(2):115-26.
45. Pettrone FA, McCall BR. Extracorporeal shock wave therapy without local anesthesia for chronic lateral epicondylitis. *J Bone Joint Surg Am.* 2005 Jun;87(6):1297-304.
46. Pleiner J, Crevenna R, Langenberger H, Keilani M, Nuhr M, Kainberger F, et al. Extracorporeal shockwave treatment is effective in calcific tendonitis of the shoulder. A randomized controlled trial. *Wien Klin Wochenschr.* 2004 Aug 31;116(15-16):536-41.
47. Porter MD, Shadbolt B. Intralesional corticosteroid injection versus extracorporeal shock wave therapy for plantar fasciopathy. *Clin J Sport Med.* 2005 May;15(3):119-24.
48. Radwan YA, EISobhi G, Badawy WS, Reda A, Khalid S. Resistant tennis elbow: shock-wave therapy versus percutaneous tenotomy. *Int Orthop.* 2008 Oct;32(5):671-7. Epub 2007 Jun 6.

49. Rompe JD, Schoellner C, Nafe B. Evaluation of low-energy extracorporeal shock wave application for treatment of chronic plantar fasciitis. *J Bone Joint Surg Am.* 2002 Mar;84-A(3):335-41.
50. Rompe JD, Decking J, Schoellner C, Nafe B. Shock wave application for chronic plantar fasciitis in running athletes. A prospective, randomized, placebo-controlled trial. *Am J Sports Med.* 2003 Mar-Apr;31(2):268-75.
51. Sabeti-Aschraf M, Dorotka R, Goll A, Trieb K. Extracorporeal shock wave therapy in the treatment of calcific tendinitis of the rotator cuff. *Am J Sports Med.* 2005 Sep;33(9):1365-8. Epub 2005 Jul 7.
52. Saw A. Extracorporeal shock wave therapy for musculoskeletal pathology--a literature review. *Med J Malaysia.* 2005 Jul;60 Suppl C:8-10.
53. Seil R, Wilmes P, Nuhrenborger C. Extracorporeal shock wave therapy for tendinopathies. *Expert Rev Med Devices.* 2006 Jul;3(4):463-70.
54. Sems A, Dimeff R, Iannotti JP. Extracorporeal shock wave therapy in the treatment of chronic tendinopathies. *J Am Acad Orthop Surg.* 2006 Apr;14(4):195-204.
55. Speed CA, Nichols D, Wies J, Humphreys H, Richards C, Burnet S, et al. Extracorporeal shock wave therapy for plantar fasciitis. A double blind randomised controlled trial. *J Orthop Res.* 2003 Sep;21(5):937-40.
56. Staples MP, Forbes A, Ptasznik R, Gordon J, Buchbinder R. A randomized controlled trial of extracorporeal shock wave therapy for lateral epicondylitis (tennis elbow). *J Rheumatol.* 2008 Oct;35(10):2038-46. Epub 2008 Sep 15.
57. Stasinopoulos D, Johnson MI. Effectiveness of extracorporeal shock wave therapy for tennis elbow (lateral epicondylitis). *Br J Sports Med.* 2005 Mar;39(3):132-6.
58. Theodore GH, Buch M, Amendola A, Bachmann C, Fleming LL, Zingas C. Extracorporeal shock wave therapy for the treatment of plantar fasciitis. *Foot Ankle Int.* 2004 May;25(5):290-7.
59. Thomson CE, Crawford F, Murray GD. The effectiveness of extra corporeal shock wave therapy for plantar heel pain: a systematic review and meta-analysis. *BMC Musculoskelet Disord.* 2005 Apr 22;6(1):19.
60. Trebinjac S, Mujic-Skikic E, Ninkovic M, Karaikovic E. Extracorporeal shock wave therapy in orthopaedic diseases. *Bosn J Basic Med Sci.* 2005 May;5(2):27-32.
61. U.S. Food and Drug Administration (FDA). Premarket approvals. Updated 2001 Mar 7. Accessed Nov 5, 2004. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>
62. U.S. Food and Drug Administration (FDA). New Device Approval. Orbasone Pain Relief System - P040039. Updated September 15, 2005. Accessed October 27, 2005. Available at URL address: <http://www.fda.gov/cdrh/mda/docs/p040039.html>
63. U.S. Food and Drug Administration (FDA). New Device Approval. Orthospec™ Extracorporeal Shock Wave Therapy - P040026. Updated September 15, 2005. Accessed October 27, 2005. Available at URL address: <http://www.fda.gov/cdrh/mda/docs/p040026.html>
64. U.S. Food and Drug Administration (FDA). New Device Approval. EMS Swiss Dolorclast® - P050004. Updated May 11, 2007. Accessed November 3, 2008. Available at URL address: <http://www.fda.gov/cdrh/mda/docs/P050004.html>
65. Wang CJ, Liu HC, Fu TH. The effects of extracorporeal shockwave on acute high-energy long bone fractures of the lower extremity. *Arch Orthop Trauma Surg.* 2007 Feb;127(2):137-42. Epub 2006 Oct 13.

66. Wang CJ, Wang FS, Yang KD, Weng LH, Ko JY. Long-term results of extracorporeal shockwave treatment for plantar fasciitis. *Am J Sports Med.* 2006 Apr;34(4):592-6.
67. Wang CJ, Chen HS. Shock wave therapy for patients with lateral epicondylitis of the elbow: a one- to two-year follow-up study. *Am J Sports Med.* 2002 May-Jun;30(3):422-5.
68. Washington State Department of Labor and Industries, Office of the Medical Director. Extracorporeal shockwave therapy for the treatment of musculoskeletal disorders. Technology assessment. Olympia, WA: Washington State Department of Labor and Industries; 2003 Jan 27. Accessed Nov 9, 2004. Available at URL address: <http://www.lni.wa.gov/ClaimsIns/Files/OMD/EswtHta20030127.pdf>
69. Weil LS Jr, Roukis TS, Weil LS, Borrelli AH. Extracorporeal shock wave therapy for the treatment of chronic plantar fasciitis: indications, protocol, intermediate results, and a comparison of results to fasciotomy. *J Foot Ankle Surg.* 2002 May-Jun;41(3):166-72.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	12/15/2007	0004	Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions
Great-West Healthcare	11/30/2007	04.210.03	Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Indications

“CIGNA” and the “Tree of Life” logo are registered service marks of CIGNA Intellectual Property, Inc., licensed for use by CIGNA Corporation and its operating subsidiaries. All products and services are provided exclusively by such operating subsidiaries and not by CIGNA Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, CIGNA Behavioral Health, Inc., Intracorp, and HMO or service company subsidiaries of CIGNA Health Corporation and CIGNA Dental Health, Inc. In Arizona, HMO plans are offered by CIGNA HealthCare of Arizona, Inc. In California, HMO plans are offered by CIGNA HealthCare of California, Inc. and Great-West Healthcare of California, Inc. In Connecticut, HMO plans are offered by CIGNA HealthCare of Connecticut, Inc. In North Carolina, HMO plans are offered by CIGNA HealthCare of North Carolina, Inc. In Virginia, HMO plans are offered by CIGNA HealthCare Mid-Atlantic, Inc. All other medical plans in these states are insured or administered by Connecticut General Life Insurance Company.

Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.