



# 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 ..... 12/15/2009**  
**Next Review Date ..... 12/15/2010**  
**Coverage Policy Number ..... 0004**

## Table of Contents

Coverage Policy .....	1
General Background .....	1
Coding/Billing Information .....	6
References .....	6
Policy History .....	11

## 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 ©2009 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 application of radial shock waves represents an alternative to focused shock wave therapy and allows for broader application (Gerdsmeier, 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 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<sup>®</sup> 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<sup>™</sup> 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<sup>®</sup> 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<sup>™</sup> (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<sup>®</sup> (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. 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 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).

In a retrospective review (n=225), Chuckpaiwong et al. (2008) reported a success rate of 77.2% at 12-months of follow-up for plantar fasciitis patients treated with high-energy ESWT. The presence of diabetes mellitus, psychological issues, and older age were found to negatively influence ESWT outcome. The study is limited by its retrospective design, lack of a control group and short-term follow-up.

A small RCT by Greve et al. (2009) compared radial shockwave treatment (n=16) and conventional physiotherapy (n=16) for plantar fasciitis. Shockwave treatment was found to be no more effective than conventional physiotherapy treatment when evaluated three months after the end of treatment.

Gerdesmeyer et al. (2008) compared radial ESWT (n=129) to placebo (n=122) for chronic plantar fasciitis in an RCT. Radial ESWT was followed by a decrease of the composite score of heel pain by 72.1% compared to 44.7% after placebo (p=0.0220). An overall success rate of 61.0% was reported for those who received radial ESWT compared to 42.2% for patients in the placebo group (p=0.0020) at 12 weeks. At 12 months of follow-up, results indicated that there was statistically significant improvement for the radial ESWT group (n=112) versus the placebo group (n=116) in the scores evaluating quality of life and function (p < 0.025).

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). At three-week follow-up, outcome measures were most improved for the maximum

tolerable energy density group. The control group had no significant changes in any outcome measures. Study limitations include the small sample size and short-term follow-up.

Wang et al. (2006) conducted a prospective RCT of 149 patients (168 heels) with chronic plantar fasciitis. The shock wave group (n=79) 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. After treatment, the shock wave group showed significantly better pain and function scores compared to the control group ( $p < 0.001$ ). No complications or device-related problems were reported. 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).

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 (ECRI, 2006).

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 (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 (Haake, et al., 2003; Buchbinder, et al., 2002). 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).

A technology assessment by the Blue Cross Blue Shield Association Technology Evaluation Center (TEC) 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 (Blue Cross Blue Shield Association TEC, 2005).

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

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).

**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:** 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:** The National Institute for Health and Clinical Excellence (NICE) issued a guidance on the use of ESWT for refractory tennis elbow. According to NICE, 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).

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. 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).

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).

### **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). A small 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 ( $p > 0.05$ ). Some studies have compared different energy levels of ESWT (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.

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.

The National Institute for Health and Clinical Excellence (NICE) issued a guidance on the use ESWT for calcific tendonitis of the shoulder. According to NICE, current evidence on the safety and efficacy of ESWT for this indication appears adequate to support the use of the procedure provided that normal arrangements are in place for consent, audit, and clinical governance (NICE, 2003b).

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
	All codes

\*Current Procedural Terminology (CPT®) ©2008 American Medical Association: Chicago, IL.

## References

1. 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](http://www.acfas.org/NR/rdonlyres/17CA33BD-A58B-40CB-9674-1392E7890076/0/ESWT_APMA_ACFASPolicyFinal_12_8_2003.pdf)
2. 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.
3. 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](http://www.bcbs.com/tec/Vol18/18_17.pdf)
4. 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](http://www.bcbs.com/tec/Vol19/19_16.pdf)
5. 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](http://www.bcbs.com/tec/Vol19/19_18.pdf)
6. Buchbinder R, Green S, Barnsley L, Smidt N, Asendelft WJ. Shock wave therapy for lateral elbow pain. *Cochrane Database Syst Rev.* 2002;(1):CD003524.
7. 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.
8. Buchbinder R. Clinical practice. Plantar fasciitis. *N Engl J Med.* 2004 May 20;350(21):2159-66.
9. 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.
10. 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.
11. 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.
12. Chuckpaiwong B, Berkson EM, Theodore GH. Extracorporeal shock wave for chronic proximal plantar fasciitis: 225 patients with results and outcome predictors. *J Foot Ankle Surg.* 2009 Mar-Apr;48(2):148-55. Epub 2009 Jan 9.
13. Crawford F, Thompson C. Interventions for treating plantar heel pain. *Cochrane Database Syst Rev.* 2003;(3):CD000416.
14. 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.
15. Gerdesmeyer L, Frey C, Vester J, Maier M, Weil L Jr, Weil L Sr, et al. Radial extracorporeal shock wave therapy is safe and effective in the treatment of chronic recalcitrant plantar fasciitis: results of a confirmatory randomized placebo-controlled multicenter study. *Am J Sports Med.* 2008 Nov;36(11):2100-9. Epub 2008 Oct 1.
16. Greve JM, Grecco MV, Santos-Silva PR. Comparison of radial shockwaves and conventional physiotherapy for treating plantar fasciitis. *Clinics (Sao Paulo).* 2009;64(2):97-103.

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. HealthTronics Surgical Services, Inc. OssaTron. Updated 2002. Accessed Nov 5, 2004. Available at URL address: <http://www.healthtronics.com>
22. Ho C. Extracorporeal shock wave treatment for chronic plantar fasciitis (heel pain). *Issues Emerg Health Technol*. 2007 Jan;(96 (part 1)):1-4.
23. Ho C. Extracorporeal shock wave treatment for chronic lateral epicondylitis (tennis elbow). *Issues Emerg Health Technol*. 2007 Jan;(96 (part 2)):1-4.
24. Ho C. Extracorporeal shock wave treatment for chronic rotator cuff tendonitis (shoulder pain). *Issues Emerg Health Technol*. 2007 Jan;(96 (part 3)):1-4.
25. 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.
26. 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.
27. 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.
28. 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.
29. Melikyan EY, Shahin E, Miles J, Bainbridge LC. Extracorporeal shock-wave treatment for tennis elbow. A randomised double-blind study. *J Bone Joint Surg Br*. 2003 Aug;85(6):852-5.
30. 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.
31. National Institute for Clinical Excellence (NICE). Interventional procedure overview of extracorporeal shockwave therapy for refractory plantar fasciitis. April 2009a. Accessed November 6, 2009. Available at URL address: <http://www.nice.org.uk/guidance/index.jsp?action=download&o=43959>
32. National Institute for Clinical Excellence (NICE). Extracorporeal shockwave therapy for refractory plantar fasciitis. Guidance. August 2009b. Accessed November 6, 2009. Available at URL address: <http://www.nice.org.uk/nicemedia/pdf/IPG311Guidance.pdf>
33. National Institute for Clinical Excellence (NICE). Interventional procedure overview of extracorporeal shockwave therapy for refractory tennis elbow. April 2009c. Accessed November 6, 2009. Available at URL address: <http://www.nice.org.uk/guidance/index.jsp?action=download&o=43959>

34. National Institute for Clinical Excellence (NICE). Extracorporeal shockwave therapy for refractory tennis elbow. Guidance. August 2009d. Accessed November 6, 2009. Available at URL address: <http://www.nice.org.uk/nicemedia/pdf/IPG311Guidance.pdf>
35. National Institute for Clinical Excellence (NICE). Interventional procedure overview of extra-corporeal shockwave lithotripsy for calcific tendonitis (tendinopathy) of the shoulder . September 2003a. Accessed November 6, 2009. Available at URL address: <http://www.nice.org.uk/guidance/index.jsp?action=download&o=30990>
36. National Institute for Clinical Excellence (NICE). Extra-corporeal shockwave lithotripsy for calcific tendonitis (tendinopathy) of the shoulder. Guidance. November 2003b. Accessed November 6, 2009. Available at URL address: <http://guidance.nice.org.uk/IPG21/PublicInfo/pdf/English>
37. 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.
38. 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.
39. 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.
40. 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 6, 2009. Available at URL address: <http://www.ohiobwc.com/downloads/blankpdf/PositionShockWaveTherapy.pdf>
41. Peters J, Luboldt W, Schwarz W, Jacobi V, Herzog C, Vogl TJ. Extracorporeal shock wave therapy in calcific tendinitis of the shoulder. *Skeletal Radiol*. 2004 Dec;33(12):712-8. Epub 2004 Oct 8.
42. 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.
43. 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.
44. 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.
45. Radwan YA, ElSobhi 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.
46. 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.
47. 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..
48. Seil R, Wilmes P, Nuhrenborger C. Extracorporeal shock wave therapy for tendinopathies. *Expert Rev Med Devices*. 2006 Jul;3(4):463-70.
49. 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.

50. 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.
51. 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.
52. 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.
53. 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.
54. 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>
55. 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>
56. 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>
57. 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>
58. 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.
59. 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.
60. 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.
61. 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, 2009. Available at URL address: <http://www.lni.wa.gov/ClaimsIns/Files/OMD/ESWT20040329.pdf>
62. 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

---

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
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.