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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Extracorporeal Shock Wave Therapy (ESWT)

- Chronic Plantar Fasciitis
- Lateral Epicondylitis (Tennis Elbow)
- Non-Union or Delayed Union Fractures

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	For Codes 0101T and 0102T - Non-Covered Services (L35008). For CPT Code 28890 - Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, “Extracorporeal Shock Wave Therapy (ESWT),” for medical necessity determinations. Use the Non-Medicare criteria below.
Local Coverage Article	None

Non-Medicare Members

Indication	Policy
Chronic Plantar Fasciitis Lateral Epicondylitis (Tennis Elbow) Non-Union or Delayed Union Fractures	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Evidence and Source Documents

Extracorporeal Shock Wave Therapy (ESWT) for Delayed or Nonunion Fractures
Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis
Extracorporeal Shock Wave Therapy (ESWT) for Lateral Epicondylitis

Background

Extracorporeal shock waves are characterized by high positive pressure with a rapid rise time and short (microsecond) duration. The shock waves are concentrated into small focal areas of 2 to 8 mm to optimize therapeutic affects and minimize the impact on adjacent tissues. There are several types of shock wave generating systems; they can involve electrohydraulic, electromagnetic or piezoelectric mechanisms. The shape of

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the pulses differs depending on the mechanism. In all of the systems, shock waves are concentrated by focusing reflectors on the target site. The shock waves can be further localized using imaging modalities such as ultrasound. Beneficial effects are expected to be observed between 6-12 weeks after treatment (Speed 2004; Wilner & Strash, 2004).

Extracorporeal shock wave therapy (ESWT) is used an a non-invasive alternative to surgery for patients with chronic plantar fasciitis who have not responded to conservative therapy such as use of orthotics, physical therapy, night splints, heel cups and treatment with non-steroidal anti-inflammatory drugs (NSAIDs). Plantar fasciitis is believed to result from a biochemical imbalance that places abnormal tension on the plantar fascia which leads to inflammation and tension on the calcaneal periosteum. The mechanism by which ESWT relieves symptoms of plantar fasciitis is not known; however, there may be an effect through tissue disruption of the tendinous fibers followed by neovascularization and replenishment of the extracellular matrix (Atkin, 1999; Wilner & Strash, 2004).

The HealthTronics OssaTron (October, 2000), Dornier Epos Ultra (January, 2002), Medispec Orthospec (April, 2005) and Orthometrix Orbasone (August, 2005) devices have all been approved by the FDA for the treatment of chronic proximal plantar fasciitis in individuals aged 18 or older who have a history of unsuccessful conservative treatments. The OssaTron and Orbasone are electrohydraulic devices, the Epos Ultra uses electromagnetic technology and the Orthospec uses sound waves.

Low-intensity ultrasound treatment was approved by the FDA in 2000 for treating non-union fractures. Healing is delayed in approximately 10% of the fractures that occur in the United States. The definitions of non-unions differ, but a fracture is generally considered to be a non-union if it has not healed by 6-9 months. Factors contributing to the occurrence of delayed unions and non-unions include the location and severity of the fracture, the extent of soft tissue damage, adequacy of stabilization or fixation, and lifestyle factors such as smoking and high alcohol intake (Hadjiargyrou et al., 1998; Biederman et al., 2003).

Some investigators believe that extracorporeal shock wave treatment (ESWT) has greater potential for treating delayed union and non-union fractures than ultrasound. Shockwaves are characterized by high positive pressure with a rapid rise time and short duration. Following the high positive pressure is an exponential decrease in pressure. The low-frequency components of shock waves allow them to pass through fluid and body tissues with less energy loss than ultrasound. Thus, shock wave treatment may be better than ultrasound for penetrating tissues and delivering adequate pressure for stimulation of bone growth (Rompe et al., 2001; Speed 2004; Wilner & Strash, 2004).

ESWT has not been approved by the FDA for treating non-union or delayed union fractures. The use of shock waves for bone repair has been studied in animal models and initial clinical studies.

Extracorporeal shock wave therapy (ESWT) is used as a non-invasive alternative to surgery for patients with soft tissue conditions including lateral epicondylitis (tennis elbow). ESWT is generally reserved for patients who have not responded to conservative therapy such as physical/occupational therapy, bracing or splinting, local steroid injections and non-steroidal anti-inflammatory drugs (NSAIDs).

Lateral epicondylitis is characterized by pain at the epicondyle on the lateral side of the elbow. The etiology is not well known, but it is generally believed to be due to musculotendinous lesions. The onset of pain can occur abruptly after an unaccustomed activity or can develop gradually in individuals who perform activities requiring repetitive and vigorous use of the forearm. Pain is often mild at first but can worsen over time (Buchbinder 2004; Melikyan, 2003).

Medical Technology Assessment Committee (MTAC)

Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis

BACKGROUND

Plantar fasciitis is the most common cause of inferior heel pain characterized by deep pain in the plantar aspect of the heel particularly on arising from the bed in the morning. While the pain may subside with activity, in some patients it persists, interrupting the activities of daily living. Approximately 10% of people develop this condition throughout their lifetime (Riddle and Schappert 2004). While the etiology has not fully been established, it is believed to result from a biomechanical abnormality that places tension on the plantar fascia and leads to inflammation and tension on the calcaneal periosteum. Several risk factors such as bone spurs, pronated foot type, obesity, limb-length discrepancy and weight-bearing appear to increase the risk of plantar fasciitis (Theodore,

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Buch et al. 2004). In the past, conservative therapies for plantar fasciitis, such as rest and stretching, have been successful (Digiovanni, Nawoczenski et al. 2006). Orthotics, physical therapy, night splints, heel cups and treatment with non-steroidal anti-inflammatory drugs (NSAIDs) have also been used in acute cases. While conservative therapies are successful in 85%-90% of patients (Gill 1997), there remain some persistent cases of plantar fasciitis. Extracorporeal shock wave therapy (ESWT) is a noninvasive intervention for patients with chronic plantar fasciitis who have not responded to conservative therapy. Thought to be an alternative to surgical intervention, the mechanism by which ESWT relieves symptoms of plantar fasciitis is not fully understood. The shock waves are believed to stimulate an extracellular response causing neovascularization, promoting tissue repair and regeneration (Atkin, 1999; Wilner & Strash, 2004). Shock waves are characterized by high positive pressure with a rapid rise time and short (microsecond) duration and are concentrated into small focal areas to optimize therapeutic effects and minimize the impact on adjacent tissues. With a variety of devices on the market, shock waves might involve electrohydraulic, electromagnetic or piezoelectric mechanisms and, in each case, the shape of the pulse differs. Beneficial effects are expected to be observed between 6-12 weeks after treatment (Speed 2004; Wilner & Strash, 2004). Please only refer to the criteria listed above for coverage determinationsconservative management). These include the HealthTronics OssaTron (October, 2000), Dornier Epos Ultra (January, 2002), Medispec Orthospec (April, 2005) and Orthometrix Orbasone (August, 2005).

12/2001: MTAC REVIEW
Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis
Evidence Conclusion: There were two RCTs evaluating shock wave generating devices for chronic plantar fasciitis. The Ogden study was the only RCT evaluating the OssaTron system. The Rompe study evaluated a similar device, the Siemens Osteostar. The Ogden study had substantial threats to validity including inadequate description of randomization and statistical analysis techniques and incomplete presentation of data. In the Ogden article, a significantly higher proportion of patients in the active treatment group than the placebo group met success criteria at 12 weeks. The Rompe study was single blind and had a small sample size; selection bias is a possibility. Rompe found a significantly greater reduction in pain in the active treatment group compared to the placebo group at 6 weeks. Neither study discussed possible adverse effects of treatment or presented long-term effectiveness data. Articles: The search yielded 10 articles. There were three empirical articles on extracorporeal shock wave treatment for chronic plantar fasciitis using the OssoTron system. One of these articles was a randomized controlled trial and 2 were case series. There were 4 articles on shock wave stimulation using devices other than the OssoTron system, 3 case series and one RCT. The two RCTs were critically appraised: Ogden JA, Alvarez R, Levitt R, Cross GL, Marlow M. Shock wave therapy for chronic proximal plantar fasciitis. Clin Orthop 2001; (387): 47-59. See Evidence Table**.** Rompe JD, Hopf C, Nafe B, Burger R. Low-energy extracorporeal shock wave therapy for painful heel: A prospective single-blind study. Arch Orthop Trauma Surg 1996; 115; 75-79. See Evidence Table.

The use of OssaTron in the treatment of chronic plantar fasciitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria for effectiveness.*

12/11/2001: MTAC REVIEW
Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis
Evidence Conclusion: A new, valid randomized controlled trial (Buchbinder et al.) did not find that treatment with extracorporeal shock wave therapy using a device made by Dornier MedTech America was more effective than placebo treatment for plantar fasciitis. The Buchbinder et al. study was stronger methodologically than previous RCTs (Ogden et al., Rompe et al.) that had suggested that extracorporeal shock wave therapy might be effective. Unlike the earlier studies, Buchbinder et al. was double blind, adequately described the statistical procedures used and did an intention to treat analysis. Buchbinder et al. provides reasonably strong evidence that extracorporeal shock wave therapy does not improve pain and function 12 weeks after treatment in patients with plantar fasciitis.
Articles: The search yielded five articles, two of which were included in the previous MTAC review. Of the three new articles, two were case series and one was a randomized controlled trial using the Dornier MedTech OPOS Ultra extracorporeal shock wave device. Buchbinder R, Ptasznit R, Gordon J. et al. Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis. JAMA 2002: 288: 1364-1372. See Evidence Table.

The use of ESWT in the treatment of chronic plantar fasciitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria for effectiveness.*

12/08/2004: MTAC REVIEW
Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis

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Evidence Conclusion: There is conflicting evidence from four double-blind, sham-controlled randomized controlled trials. According to primary outcome assessment at 12 weeks, two of the RCTs reviewed (Buchbinder; Haake) did not find that ESWT was significantly more effective than a sham intervention at 12 weeks while the other two (Theodore; Ogden) did find a significant benefit of ESWT. It is not clear why findings varied. Clinical experts have stated the belief that efficacy is dependent on machine types and study protocols. Three studies used Dornier shock wave devices and the fourth (Ogden) used the OssaTron device. Three studies (all except Buchbinder) only included patients who had failed conservative therapy. The total number of shocks delivered was 2000-4000 in the negative studies and 1500-3800 in the positive studies. The energy of individual impulses may have been lower in the negative studies. Haake used shock waves of 0.08 mJ/mm2 and in Buchbinder, shockwaves varied between 0.02-0.33 mJ/mm2. In the positive studies, shock waves were 0.22 mJ/mm2 and 0.36 mJ/mm2. There were financial links with the device manufacturer in the positive studies, and there did not appear to be links in the negative studies. The studies either had a total of 12 weeks follow-up, or patients were unblinded at 12 months and eligible for other treatments. Therefore, high-quality comparative data on the effectiveness of ESWT beyond 12 weeks are not available. None of the studies reported serious adverse effects associated with ESWT.
Since the highest grade of evidence in previous reviews of this item was randomized controlled trials (RCTs), only RCTs and meta-analyses of RCTs were considered for the update. Ideally, RCTs of shock wave therapy for plantar fasciitis would have the following characteristics: Use a commercially available device Sham-controlled, or use of alternative treatment Double-blind Sufficient statistical power No financial conflicts of interest Long-term follow-up for efficacy and safety
Articles: The search yielded 18 articles, several of which were reviews. There were six publications reporting on five randomized controlled trials (two articles on the same study) and a meta-analysis of both controlled and uncontrolled studies. The meta-analysis was excluded because it was not limited to controlled studies, and only considered articles published through 2000, prior to the initial MTAC review. Three sham-controlled RCTs with sufficient statistical power were critically appraised. One RCT was excluded because it was not sham-controlled and another because it had a small sample size and no evaluation of statistical power. The studies reviewed include: Haake M, Buch M, Schoellner C et al. Extracorporeal shock wave therapy for plantar fasciitis: randomized controlled multicentre trial. BMJ 2003 327:75. See Evidence Table.Theodore GH, Buch M, Amendola A. et al. Extracorporeal shock wave therapy for the treatment of plantar fasciitis. Foot Ank Int 2004; 25: 290-297. See Evidence Table. Ogden JA, Alvarez RG, Levitt RL et al. Electrohydraulic high-energy shock wave treatment for chronic plantar fasciitis. J Bone Joint Surg 2004; 86-A: 2216-2228. See Evidence Table. Buchbinder R, Ptasznit R, Gordon J. et al. Ultrasound-guided extracorporeal shock wave therapy for plantar fasciitis. JAMA 2002: 288: 1364-1372. See Evidence Table.

The use of ESWT in the treatment of chronic plantar fasciitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria for effectiveness.*

04/02/2007: MTAC REVIEW
Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis
Evidence Conclusion: There is some new evidence that ESWT treatment is effective in the short-term (3 months) for treating chronic plantar fasciitis that is unresponsive to conservative therapies. Both randomized controlled trials reviewed for the 2007 MTAC update found significantly greater reduction in pain after 3 months with active ESWT treatment compared to a placebo intervention. Overall, the findings from double-blind placebo-controlled RCTs are mixed. Some, including the two recent studies, have found a significant benefit with ESWT treatment whereas other studies did not. Studies have varied in the type of design used and the protocol e.g. number of sessions, energy level, number of shocks delivered, etc. The positive studies such as the two new studies, but not the negative studies, appear to have financial links with the device manufacturer, although specific biases introduced by industry funding were not identified. The absolute benefit of ESWT in statistically significant studies tended to be small, e.g. 1 point or less difference between groups on a 10-point visual analogue scale. Evidence of long-term effectiveness is lacking. None of the RCTs had blinded assessment of pain outcomes beyond 3 months. None of the studies reported serious adverse effects associated with ESWT. No Cochrane collaboration meta-analysis was identified. The Kaiser Interregional New Technology Committee (INTC) reviewed this topic in November, 2006 and concluded that there was insufficient evidence of efficacy based on methodological limitations of studies and lack of long-term follow-up. New RCTs identified in the literature search were screened using the same criteria as in the previous MTAC review. These criteria are: Use of a commercially available device Included patients who meet FDA approved indication for treatment Sham-controlled, or use of alternative treatment Double-blind Sufficient statistical power No financial conflicts of interest Long-term follow-up for efficacy and safety

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Articles: Four double-blind sham-controlled RCTs have been reviewed by MTAC (Haake et al., 2003; Theodore et al., 2004; Ogden et al., 2004; Buchbinder et al. 2002). Two additional double-blind sham-controlled RCTs conducted with patients who had failed conservative therapy for at least 6 months were identified. Both used commercially available devices. Neither study had long-term follow-up of effectiveness or had financial links with the device manufacturers. These two studies were critically appraised. Other new RCTs were excluded from further review. Two studies (Porter and Shadbolt, 2005; Wang et al., 2006) used ESWT as the initial treatment, not an FDA-approved indication. Another RCT (Rompe et al., 2005) compared two techniques for delivering ESWT; there was no comparison group that did not receive shockwave treatment. References for the critically appraised studies are as follows: Malay DS, Pressman MM, Assili A et al. Extracorporeal shockwave therapy versus placebo for the treatment of chronic proximal plantar fasciitis: Results of a randomized, double-blinded, multicenter intervention trial. J Foot & Ankle Surg 2006; 45(4): 196-210. See Evidence Table. Kudo P, Dainty K, Clarfield M et al. 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; 24: 115-123. See Evidence Table.

The use of ESWT in the treatment of chronic plantar fasciitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

04/21/2014: MTAC REVIEW
Extracorporeal Shock Wave Therapy (ESWT) for Chronic Plantar Fasciitis
Evidence Conclusion: While the 2007 MTAC review identified two RCTs to support short-term effectiveness of ESWT when compared with placebo, the cumulative body of evidence (including four RCTs from previous reviews) was conflicting and lacked support of long-term effectiveness. The current literature search identified one meta-analysis pooling data from seven RCTs specifically aimed at examining the effectiveness of ESWT compared to placebo. Three additional trials were identified that compare ESWT to endoscopic plantar fasciotomy (EPF). The meta-analysis by Aqil and colleagues included seven RCTs with strict inclusion criteria. Due to differences in outcome measures and follow-up timeframes, pooled analysis of only four of the included studies was possible. Ultimately, ESWT had favorable results compared with placebo with five of the six included studies reaching significance after short term follow up (12 weeks). (Aqil, Siddiqui et al. 2013). Saxena et al. treated 25 athletes experiencing chronic plantar fasciitis with EPF, ESWT or placebo ESWT (P-ESWT). At one year follow up, the overall Visual analogue Scale (VAS) and Roles and Maudsley (RM) scores showed statistical improvement within both the EPF and ESWT groups. Treatment outcomes in the EPF group were significantly better than both ESWT and P-ESWT. The investigators report, however, that patients enrolled in ESWT were able to continue with their exercise regimen, while the EPF group were delayed in their return to athletic activity by 2.8 months on average (Saxena, Fournier et al. 2013). Radwan and colleagues randomized 65 patients to either ESWT or EPF for the treatment of resistant plantar fasciitis. At follow-up (3 weeks, 3 months and 12 months), both groups achieved progressive improvements, however, the majority of improvements in the ESWT group were seen between week three and week 12 while the EPF group saw more improvement lasting from week three to 12 months post-intervention. With that said, there were no significant differences detected between groups through the different time periods for any measured parameter except for the AOFAS maximum walking distance and gait sub-scores at three weeks (ESWT group p=005 and EPF group, p=002) (Radwan, Mansour et al. 2012). Finally, in 2010 Othman and colleagues prospectively evaluated 37 patients with chronic plantar fasciitis who self-selected either EPF or ESWT treatment after discussion of possible outcomes. Their results maintain similar trends with slightly better results seen in the EPF group but identification of the ESWT intervention as the preferred treatment option due to the benefits of no complications, no immobilization and earlier return to work (Othman and Ragab 2010). In general, study quality was good with randomization and appropriate comparison groups. For the most part, outcome measures were consistent throughout the selected literature, however, the intensity and the frequency of ESWT application varied and sample sizes were relatively small. The results from the recent meta-analysis provide evidence to suggest that ESWT is a safe and effective treatment of chronic plantar fasciitis compared to placebo in the short term. When compared to surgical intervention, however, ESWT does not perform as well. EPF produces better outcomes but is associated with morbidities such as prolonged healing, loss of time from work, nerve injury and tarsal instability. **Conclusion**: There is insufficient evidence from large, well design randomized trials that ESWT is an effective treatment for chronic plantar fasciitis. There is insufficient evidence to support the safety of ESWT as a treatment option for chronic plantar fasciitis. **Articles:** The literature search revealed over 200 publications which included systematic reviews and practice recommendations. After articles were screened for randomization and outcome comparison one meta-analysis pooling data from RCTs and three RCTs/clinically controlled trials that compared ESWT with the surgical intervention, endoscopic plantar fasciotomy (EPF), were identified. The following articles were selected for critical appraisal: Aqil A, Siddiqui MRS, Solan M, Redfern DJ, Gulati V, Cobb JP. Extracorporeal shock wave therapy is effective in treating chronic plantar

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fasciitis: a meta-analysis of RCTs. Clinical Orthopedic Related Research 2013;471:3645-3652. See Evidence Table. Saxena A, Fournier M, Gerdesmeyer L, Gollwitzer H. Comparison between extracorporeal shockwave therapy, placebo ESWT and endoscopic plantar fasciotomy for the treatment of chronic plantar heel pain in the athlete. Muscles, Ligaments and Tendons Journal 2012;2(4):312-316. See Evidence Table. Radwan YA, Mansour AMR, Badawy WS. Resistant plantar fasciopathy: shock wave versus endoscopic plantar fascial release. International Orthopaedics 2012;36:2147-2156. See Evidence Table. Othman AMA, Ragab EM. Endoscopic plantar fasciotomy versus extracorpeal shock wave therapy for treatment of chronic plantar fasciitis. Arch Orthop Trauma Surg 2010;130:1343-1347. See Evidence Table.

The use of ESWT in the treatment of chronic plantar fasciitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

Extracorporeal Shock Wave Therapy (ESWT) for Lateral Epicondylitis

BACKGROUND

Extracorporeal shock waves are characterized by high positive pressure with a rapid rise time and short (microsecond) duration. The shock waves are concentrated into small focal areas of 2 to 8 mm to optimize therapeutic effects and minimize the impact on adjacent tissues. There are several types of shock wave generating systems; they can involve electrohydraulic, electromagnetic or piezoelectric mechanisms. The shape of the pulses differ depending on the mechanism. In all of the systems, shock waves are concentrated by focusing reflectors on the target site. The shock waves can be further localized using imaging modalities such as ultrasound. Beneficial effects are expected to be observed between 6-12 weeks after treatment (Speed 2004; Wilner & Strash, 2004). Extracorporeal shock wave therapy (ESWT) is used as a non-invasive alternative to surgery for patients with soft tissue conditions including lateral epicondylitis (tennis elbow). ESWT is general reserved for patients who have not responded to conservative therapy such as physical/occupational therapy, bracing or splinting, local steroid injections and non-steroidal anti-inflammatory drugs (NSAIDs). Lateral epicondylitis is characterized by pain at the epicondyle on the lateral side of the elbow. The etiology is not well known, but it is generally believed to be due to musculotendinous lesions. The onset of pain can occur abruptly after an unaccustomed activity or can develop gradually in individuals who perform activities requiring repetitive and vigorous use of the forearm. Pain is often mild at first but can worsen over time (Buchbinder 2004; Melikyan, 2003). Two ESWT devices, the Siemens Sonocur (July, 2002) and the HealthTronics OssaTron (March, 2003) have been approved by the FDA for the treatment of chronic lateral epicondylitis in individuals age 18 or older who have a history of unsuccessful conservative treatments. The OssaTron is an electrohydraulic device and the Sonocur uses electromagnetic technology. Extracorporeal shockwave therapy for epicondylitis was previously reviewed by MTAC in February,2005 and did not meet MTAC evaluation criteria.

02/07/2005: MTAC REVIEW

Extracorporeal Shock Wave Therapy (ESWT) for Lateral Epicondylitis

Evidence Conclusion: This review evaluated ESWT for patients with epicondylitis who had failed conservative therapy. Three double blind sham-controlled RCTs were identified, with mixed findings. The Melikyan and Haake studies did not find significant differences between the active treatment and control group on any outcome measure. Rompe found that the group receiving active ESWT had a significantly better outcome at 3 months. Pain reduction but not function was better in the treatment group at 12 months. The Melikyan study may have been underpowered (did not discuss power), but the Haake and Rompe studies were planned to have sufficient sample sizes to detect clinically significant differences. Differences in study methodology include whether the use of concurrent conservative treatments was allowed, whether local anesthesia was used during ESWT and the specific shockwave devices used. In the Haake study, patients were not restricted from using conservative treatments after ESWT. Rompe permitted use of other treatments after 3 months. Melikyan did not mention use of additional treatments. The Haake study used local anesthesia during the intervention, but Rompe and Melikyan, one positive and one negative study, did not. (Anesthesia may make it more difficult to locate the area of greatest pain). The Rompe study used the Siemens SONOCUR plus, Melikyan used the Dornier Epos Ultra and Haake used both of these. There were eight articles reporting on seven randomized controlled trials (two publications on the same study). In addition, there was a Cochrane Library review of randomized controlled trials conducted in 2001. The Cochrane review included only two trials, too few for a meaningful meta-analysis. Most of the RCTs identified were published after the Cochrane Review was completed. Individual RCTs were considered for critical appraisal. Ideally, RCTs of shock wave therapy for epicondylitis would have the following characteristics: Use a commercially available device, Include patients who meet FDA approved indication for treatment, Sham-controlled, or use of alternative treatment, Double-blind, Sufficient statistical power, No financial conflicts of interest, Long-term follow-up for efficacy and safety

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Articles: Three of the six RCTs included patients who met the FDA approval criterion of a history of unsuccessful conservative treatment. All of these were double-blind, sham-controlled, used commercially available devices and did not report significant financial conflicts of interest. These three RCTs (four articles) were critically appraised, the citations are as follows: Melikyan EY, Shahin E, Miles J et al. Extracorporeal shock-wave treatment for tennis elbow. J Bone Joint Surg (Br) 2003; 85-B: 852-855. See Evidence Table. Haake M, Konig IR, Decker T. et al. Extracorporeal shock wave therapy in the treatment of lateral epicondylitis. J Bone Joint Surg 2002; 84-A: 1982-1991. Additional data reported in Haake et al. Arch Orthop Trauma Surg 2002; 122: 222-228. See Evidence Table Rompe JD, Decking J. Schoellner C et al. Repetitive low-energy shock wave treatment for chronic epicondylitis in tennis players. Am J Sports Med 2004; 32: 734-743. See Evidence Table.

The use of extracorporeal shock wave treatment in the treatment of lateral epicondylitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

04/02/2007: **MTAC REVIEW**
Extracorporeal Shock Wave Therapy (ESWT) for Lateral Epicondylitis
Evidence Conclusion: A Cochrane collaboration review concluded that shock wave therapy provides little or no benefit in terms of pain and function in epicondylitis. In meta-analyses of 2 to 3 studies each, shockwave therapy was not significantly better than placebo for the vast majority of outcomes. A limitation of the Cochrane review was that, due to differences in study methods, summary estimates could be obtained only for a few studies at a time, not for all of the trials they identified. Several of the RCTs included in the Cochrane review were examined in greater depth. Three double-blind sham-controlled RCTs, conducted among patients who had failed conservative therapy, were evaluated for the 2005 MTAC review. Findings were mixed. Two studies did not find significant differences between the active treatment and control group on any outcome measure; one of these may have been underpowered. The third found that the group receiving active ESWT had a significantly better outcome at 3 months, and pain reduction but not function was better in the treatment group at 12 months. One additional well-conducted RCT with patients who had failed conservative treatment was identified for this update (Pettrone et al., 2005). The Pettrone study, in which no local anesthesia was used, found that ESWT was significantly more effective than placebo at reducing pain 50% or more after 12 weeks (61% in shockwave group, 29% in placebo group). The new study appeared to be the only RCT evaluated for MTAC in which the authors received a substantial financial contribution from the manufacturer. The body of literature on shockwave therapy for epicondylitis does not permit a clear conclusion about efficacy. Findings from RCTs are contradictory, and a Cochrane review concluded that treatment provides little or no benefit. Differences in outcome may be due in part to variability in study design e.g. type of device, whether or not local anesthesia was used and whether use of any conservative treatments were permitted after ESWT. A Canadian brief technology assessment that searched the literature through March, 2005 was identified (CADTH, 2007). There was no quantitative meta-analysis. The authors concluded that results from RCTs have been conflicting. A Cochrane collaboration systematic review was identified that included literature published through February, 2005. The meta-analysis in the Cochrane review was of limited scope due to the inability to combine trials with varying methodology e.g. different outcome measures, time frames for analysis, etc. Due to the limited meta-analysis in the Cochrane review, individual RCTs were also examined for this MTAC update. For the previous MTAC review, the following criteria were used to identify the strongest and most relevant RCTs:Use of a commercially available device, Included patients who meet FDA approved indication for treatment, Sham-controlled, or use of alternative treatment, Double-blind, Sufficient statistical power, No financial conflicts of interest, Long-term follow-up for efficacy and safety
Articles: In 2005, the 3 RCTs that most closely met the above criteria were critically appraised. Other RCTs screened at that time did not include patients meeting the FDA-approved criterion of a history of unsuccessful conservative treatment. One new RCT was identified that was placebo-controlled, double-blind, used a commercially available device (Sonocur) and included patients who had failed conservative treatment. The Cochrane review and new RCT were critically appraised: Buchbinder R, Green SE, Youd JM. Shockwave therapy for lateral elbow pain. Cochrane Library 2007: Volume 1. Date of most recent update: March, 2006. See Evidence Table.

The use of extracorporeal shock wave treatment in the treatment of lateral epicondylitis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

Extracorporeal Shock Wave Therapy (ESWT) for Delayed or Nonunion Fractures
BACKGROUND
Healing is delayed in approximately 10% of the fractures that occur in the United States. The definitions of non unions differ, but a fracture is generally considered to be a non-union if it has not healed by 6-9 months. Factors contributing to the occurrence of delayed unions and non-unions include the location and severity of the fracture,

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the extent of soft tissue damage, adequacy of stabilization or fixation, and lifestyle factors such as smoking and high alcohol intake (Hadjiargyrou et al., 1998; Biederman et al., 2003). Low-intensity ultrasound treatment was approved by the FDA in 2000 for treating non-union fractures. Some investigators believe that extracorporeal shock wave treatment (ESWT) has greater potential for treating delayed union and non-union fractures than ultrasound. Shockwaves are characterized by high positive pressure with a rapid rise time and short duration. Following the high positive pressure is an exponential decrease in pressure. The low-frequency components of shock waves allow them to pass through fluid and body tissues with less energy loss than ultrasound. Thus, shock wave treatment may be better than ultrasound for penetrating tissues and delivering adequate pressure for stimulation of bone growth (Rompe et al., 2001; Speed 2004; Wilner & Strash, 2004). ESWT has not been approved by the FDA for treating non-union or delayed union fractures. The use of shock waves for bone repair has been studied in animal models and initial clinical studies. MTAC has not previously reviewed ESWT for treating delayed or non-union fractures.

02/07/2005: MTAC REVIEW
Extracorporeal Shock Wave Therapy (ESWT) for Delayed or Nonunion Fractures
Evidence Conclusion: There is insufficient evidence to determine whether extracorporeal shock wave treatment is effective for treating delayed unions and non-unions. Only case series data were available; these described the proportion of cases that healed at the end of the study period. Since the studies did not include concurrent comparison or control groups, it is not possible to know what the healing rate in these groups of patients would have been without the shock wave intervention. The authors of both studies that were reviewed called for controlled studies to be conducted. Treatment of delayed unions or non-unions are not FDA-approved indications for ESWT. The search yielded 19 articles, some of which were on related treatments or related conditions. Ideally, studies on the effectiveness of shock wave therapy would have the following characteristics:Randomized controlled trial, Use a commercially available device, Include patients who meet FDA approved indication for treatment, Sham-controlled, or use of alternative treatment, Double-blind, Sufficient statistical power, No financial conflicts of interest, Long-term follow-up for efficacy and safety
Articles: There were no randomized or non-randomized controlled studies. The empirical literature consisted of two prospective and one retrospective case series. The two prospective case series were critically appraised. The citations for the reviewed articles are as follows: Biedermann R, Martin A, Handle G et al. Extracorporeal shock waves in the treatment of nonunions. J Trauma 2003; 54: 936-942. See Evidence Table. Rompe JD, Rosendhl T, Schollner C et al. High-energy extracorporeal shock wave treatment of nonunions. Clin Orthoped Rel Res 2001; 387: 102-111. See Evidence Table.

The use of extracorporeal shock wave treatment in the treatment of delayed union or nonunion fractures does not meet the *Kaiser Permanente Medical Technology Assessment Criteria* for effectiveness.

Creation Date	Review Dates	Date Last Revised
12/12/2001	04/06/2010 MDCRPC, 02/11/2011 MDCRPC, 12/06/2011 MDCRPC,10/02/2012MDCRPC, 08/06/2013MPC, 06/03/2014MPC, 04/07/2015MPC, 02/02/2016MPC, 12/06/2016MPC, 10/03/2017MPC ,08/07/2018MPC	04/02/2007

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L35008
07/18/2018	Removed coverage statement for FEHB, Changed the Medicare coverage language for code 28890

Codes

CPT 28890; 0101T; 0102T; 0299T; 0300T

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