Clinical Policy Bulletin:
Plantar Fasciitis Treatments

Revised February 2015

Number: 0235

Policy

Aetna considers endoscopic plantar fasciotomy medically necessary as an alternative to conventional open plantar fasciotomy for members with intractable plantar fasciitis or heel spur syndrome who have failed a 6-month trial of conservative therapy.

Aetna considers extracorporeal shock-wave therapy (ESWT) with the OssaTron (HealthTronics, Marietta, GA), the Dornier Epos Ultra (Dornier Medical Systems, Kennesaw, GA), the Sonocur (Siemens Medical Solutions Inc., Iselin, NJ), the Orbasone Pain Relief System (Orthometrix, Inc., White Plains, NY), the OrthospecTM Extracorporeal Shock Wave Therapy (Medispec, Ltd., Germantown, MD), or any other ESWT devices experimental and investigational for plantar fasciitis because their effectiveness has not been established.

Aetna considers the following approaches (not an all-inclusive list) experimental and investigational for members with plantar fasciitis because there is a lack of reliable published literature documenting the safety and efficacy of these techniques in the treatment of plantar fasciitis:

- Autologous blood/growth factor injection
- Botulinum toxin Cryosurgery (cryotherapy), Intracorporeal pneumatic shock therapy
- Kinesio taping/elastic therapeutic taping
- Low-level laser therapy
- Marrow stimulation techniques (microfracture, drilling)
- Micronized dehydrated amniotic/chorionic membrane allograft
- Platelet rich plasma/growth factor injection
- Pulsed radiofrequency electromagnetic field therapy
- Radiofrequency lesioning
- Radiotherapy
- Trigger point dry needling.
Background

Plantar fasciitis is defined as the traction degeneration of the plantar fascia at its origin on the heel. Plantar fasciitis is the most common cause of chronic heel pain. It is usually caused by bone spurs or inflammation of the foot's connective tissue and the condition may be resistant to conservative treatment. Conservative treatments for plantar fasciitis include rest, physical therapy, heel cushions, non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroid injections, taping, foot orthotics (2nd line conservative treatment), shoe modifications, night splinting, and casting.

Surgical intervention may be indicated for patients who fail conservative treatment. Well-designed placebo- or sham-controlled clinical trials for plantar fasciitis are especially important because: (i) most cases of plantar fascial pain resolve spontaneously over time; and (ii) pain is a symptom that is especially susceptible to placebo effects.

Radiofrequency lesioning is used to ablate pain pathways and is generally employed for intractable pain that has not responded to conservative measures. Radiofrequency lesioning is not an established procedure for the treatment of plantar fasciitis.

Most recently, extracorporeal shock wave therapy (ESWT) has been used to treat plantar fasciitis. Extracorporeal shock wave therapy is thought to relieve pain by disrupting scar tissue, causing microscopic damage to that tissue. This induces new blood vessel formation into the injured area and facilitates the healing process.

The Dornier EPOS Ultra is an ESWT system that uses electromagnetic energy to generate a shock wave, which travels through a water-filled coupling cushion mounted to a therapy head. The therapy head has an acoustic lens to focus the shock wave treatment on the target tissue. The EPOS Ultra also has an ultrasound imaging system that is used to observe and monitor the shock wave treatment. Typically, 3,800 shock waves are delivered over 20 mins.

In support of their pre-market approval application (PMA), a randomized, double-blind, sham-treatment-controlled study was conducted involving 150 adult patients with chronic plantar fasciitis enrolled at 6 clinical centers. Patients had at least moderate pain (visual analog score [VAS] greater than 5) for at least 6 months and a history of prior conservative therapy (including NSAIDs and 2 other conservative therapies). After being randomized to active or sham treatment groups, patients underwent a single ESWT session, and were followed for 12 months. After 3
months, patients who received sham treatment were offered active unmasked treatment. To maintain physician blinding during the first 3 months of the study, the treatment was administered by a physician who did not perform the follow-up evaluations.

Although there was a modest, statistically significant difference in improvement in VAS pain scores from baseline (the primary study endpoint) between active and sham treatment groups at 3 months, this was not accompanied by a significant improvement of function. In the active group, the pain score decreased by an average of 56.5% by the end of 3 months; in the sham group, the average pain score decreased by 46.6%. Patients in the active group were more likely (56%) than patients in the sham group (45%) to report an improvement in VAS pain scores of 60% or more from baseline; however, this difference was not statistically significant. There was a statistically significant difference in patient satisfaction ( Roles and Maudsley pain scores) between treatment groups, with 62% of active patients with good to excellent results, compared to 40% of sham patients. However, there was no statistically significant difference between active and placebo groups with respect to function (American Orthopaedic Foot and Ankle Society [AOFAS] Ankle-Hindfoot Scale (a validated rating scale which incorporates assessment of function (50%), pain (40%), and alignment (10%)). There was also no statistically significant difference between active and placebo treated groups with respect to a measure of general health status (SF12 Health Status Questionnaire (patient's self-assessment of general health status and mental condition)).

The most common complication was pain during treatment, which occurred in 72.4% of active patients and 6.8% of sham patients. The investigators assessed the likelihood that patient blinding was maintained during the study, given difference in treatment-induced pain between active and sham treatments. After the ESWT session, the investigators asked patients in each treatment group whether they experienced pain during treatment, and had them guess as to whether they had been assigned to active or sham treatment. Sixty percent of patients in the active group correctly guessed that they received active treatment, and 40% were unsure. In the sham group, 15% of patients correctly guessed that they received sham treatment, and 85% believed that they received an active treatment or were unsure. Active patients who reported pain during treatment were more likely to have correctly guessed their assignment than active patients who reported no pain; however, there was no significant difference at follow-up in change in VAS score from baseline between active patients who believed they received active treatment and active patients who believed they received a sham treatment.

Other complications included pain 3 to 5 days after treatment, which was reported in 41% of patients in the active group; however, there was no statistically significant difference between active and sham groups, as 35% of patients in the sham group also reported pain 3 to 5 days after treatment. Other than pain during treatment, there were no significant differences in the nature or type of adverse events reported between active and sham treatment groups.

The OssaTron uses an electrohydraulic method of generating shock waves, which are focused so that they converge at a point near the surface of the foot.
Typically, 1,500 shocks are necessary for treatment, which is performed on an outpatient surgical center under local or general anesthesia.

In support of their pre-market application, the manufacturer of the OssaTron submitted to the Food and Drug Administration (FDA) the results of a clinical trial involving 300 patients with plantar fasciitis that was not adequately responsive to conservative treatments. Patients were randomly assigned to the active extracorporeal shock wave therapy or sham treatment. Patients were evaluated on the 4 following criteria: (i) investigator assessment of heel pain, with positive response defined as greater than 50% improvement over baseline and a VAS score of 4 or less on a 10-point scale; (ii) the patient's self-assessment of pain, with a positive response defined as greater than 50% improvement over baseline and a VAS score of less than 4; (iii) the patient's self-assessment of activity, with a positive response defined as improvement of 1 point on a 5-point scale, or maintenance of a baseline score of 0 or 1; and (iv) use of pain medications, with a positive response defined as no use of pain medications for heel pain. After 12 weeks, the only clinically significant difference between active and sham treatments was in the investigator assessment of heel pain: 46% of the OssaTron-treated patients and 30% of the sham-treated patients had an improvement of more than 5.0 units on a 10-unit VAS at 12 weeks, as assessed by the investigator. However, the self-assessed pain score showed only marginal differences between the treatment and placebo groups, and the other 2 endpoints -- self-assessment of activity and use of pain medications -- were not statistically different between the 2 groups. Side effects of Ossatron ESWT included nerve complications (nerve irritation, numbness) in 6 patients and plantar fascial tears in 2 patients. The FDA is requiring a study to further evaluate these adverse effects.

In a randomized controlled study (n = 160), Buchbinder et al (2002) found no evidence to support a beneficial effect on pain, function, and quality of life of ultrasound-guided ESWT over placebo in patients with ultrasound-proven plantar fasciitis 6 and 12 weeks following treatment. Commenting on the results of the study by Buchbinder and colleagues, Ham and Strayer (2002) stated that “[e]xtracorporeal shock wave therapy cannot be recommended to improve pain and function in patients with plantar fasciitis based on the results of this study. Although previous studies do report a benefit from ESWT, this study appears to represent a higher level of evidence than was previously available for evaluating the efficacy of this therapy. An updated meta-analysis combining all the studies on ESWT will be useful”.

Aetna's policy on the unproven status of ESWT for plantar fasciitis is supported by the conclusions of more than 12 systematic evidence reviews, including those from national and international authorities (including the Cochrane Collaboration (Crawford and Thomson, 2010), BMJ Clinical Evidence (Landorf and Menz, 2007), the Washington State Department of Labor and Industries (2003), the BlueCross BlueShield Association Technology Evaluation Center (2003, 2005), the Institute for Clinical Systems Improvement (2004), the California Technology Assessment Forum (Tice, 2004; CTAF, 2007; CTAF, 2009), the National Institute for Health and Clinical Excellence (2005), BMC Musculoskeletal Disorders (Thomson et al, 2005), the Canadian Agency for Drugs and Technologies in Health (Ho, 2007), and the Galacian Agency for Health Technology Assessment (Ruano-Ravina,
These systematic evidence reviews of ESWT for plantar fasciitis have concluded that the effectiveness of this intervention is unknown. Pain associated with ESWT and differences in procedures mean that blinding in placebo- or sham-controlled trials is probably not maintained. Rajkumar and Schmitgen (2002) concluded that additional controlled studies are required to define the precise role of this new modality in the treatment of chronic plantar fasciitis.

An assessment of ESWT for plantar fasciitis 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."

In a double-blind randomized controlled study (n = 88), Speed et al (2003) concluded that there appears to be no treatment effect of moderate dose ESWT in subjects with plantar fasciitis. The investigators stated that further research is needed to develop evidence based recommendation for the use ESWT in musculoskeletal complaints. This is in agreement with findings of a study by Haake et al (2003) (n = 272) who reported that ESWT is ineffective in the treatment of chronic plantar fasciitis.

The BlueCross BlueShield Association Technology Evaluation Center (BCBSA, 2003) re-assessed ESWT for plantar fasciitis, and reversed position on the effectiveness of this therapy. The 2003 TEC assessment stated: "[i]n summary, the available evidence consists largely of good quality studies; there are 3 double-blind, randomized controlled trials that included over 600 patients. Overall, the results of the trials are inconclusive. If ESWT provided a clinically significant improvement in plantar fasciitis, one would expect consistent improvement across multiple ways of measuring pain and function (e.g., morning pain, use of pain medications, ability to walk without pain). However, the results of various measures within studies and across studies do not give a consistent picture concerning the effect of ESWT on health outcomes for plantar fasciitis." The TEC assessment (BCBSA, 2003) concluded that "[t]he evidence is not sufficient to permit conclusions on the health outcome effects of ESWT" for plantar fasciitis. The BlueCross BlueShield Association Technology Evaluation Center re-affirmed their position in a subsequent assessment published in 2005 (BCBSA, 2005).

In an evidence review of plantar fasciitis treatments published in the New England Journal of Medicine, Buchbinder (2004) concluded that "the available data do not provide substantive support for [the] use" of ESWT for plantar fasciitis.

Although recent reports seem to provide evidence that ESWT may be effective in the treatment of plantar fasciitis, there are drawbacks in these studies. The study by Odgen et al (2004) appears to be a follow-up report on the same patients in their previous reports, providing data on 1-year and longer. Theodore et al (2004) concluded that ESWT represents a safe treatment option for chronic plantar fasciitis. In the study by Theodore et al, there was a significant difference (p = 0.0435) in VAS at 3-month between the 2 groups: 3.4 +/- 2.7 for the treatment group and 4.1 +/- 3.1 for the control group. There appears to be a wide overlap of VAS between the 2 groups. Furthermore, it is unclear whether these small
differences are clinically significant as indicated by the lack of difference in VAS during the first few mins of walking in the morning between the 2 groups. There are also no differences in AOFAS and SF-12 health status questionnaire scores between the 2 groups. In addition, it is of note that there were no differences in Roles and Maudsley Score at 6-week follow-up between the 2 groups. Moreover, 38.4 % of patients in the treatment group reported a fair to poor Roles and Maudsley Score at 3-month compared to only 6.3 % of their counterparts in the control group. More importantly, it is unclear why the study was unblinded at 3 months. It would have been interesting to have the patients in the control group remained in the original protocol and compared their results with those from the treatment group at 12-month.

A technology assessment by the Institute for Clinical Systems Improvement (2004) concluded that "[t]he scientific evidence, to date, does not permit a conclusion to be reached regarding the efficacy of ESWT for plantar fasciitis." This is in agreement with the assessment by the BlueCross BlueShield Association’s Technology Evaluation Center (2005), which concluded that ESWT for chronic plantar fasciitis has not been demonstrated to improve health outcomes in the investigational setting. Thus, ESWT for chronic plantar fasciitis does not meet the TEC criteria.

An assessment of ESWT for musculoskeletal disorders prepared for the California Technology Assessment Forum (CTAF) stated that ESWT for plantar fasciitis does not meet CTAF’s assessment criteria (Tice, 2004). The assessment explained that plantar fasciitis tends to improve over extended periods of time, even for patients who have failed conservative therapy for several months. Therefore, uncontrolled studies of ESWT for plantar fasciitis were promising, but may represent mainly the natural history of this disorder abetted by a strong placebo effect. The CTAF assessment explained that studies with pain as the primary outcome commonly are subject to large placebo effects (Tice, 2004). The assessment observed that, in the non-blinded randomized controlled trials of ESWT, the placebo group usually reported minimal improvements while the placebo group in the well-blinded studies reported 30 to 50 % improvements in pain scores. The assessment stated that this observation highlights the need for high quality, double-blinded, randomized trials as the minimum standard of evidence for ESWT in plantar fasciitis. The CTAF assessment noted that the 9 randomized controlled clinical trials of ESWT for plantar fasciitis illustrate this point (Tice, 2004). The assessment found “a tremendous amount” of variability in the quality of the randomized trials and in the interventions studied. The assessment found that the fair to poor quality studies demonstrated benefit compared with sham or delayed therapy, but the trials were generally small, with inadequate blinding, poor allocation concealment, and differential loss to follow-up, which could have biased the study results in favor of ESWT. In contrast, the assessment found that the 2 good quality studies found no evidence for benefit compared with sham ESWT.

The CTAF re-assessed the evidence for ESWT for plantar fasciitis, and found that this does not meet CTAF criteria (Tice, 2009). The CTAF assessment explained that patients with plantar fasciitis tend to improve over extended periods of time, even patients who have failed conservative therapy for months. Therefore, the uncontrolled studies of ESWT, while promising, may represent
mainly the natural history of the disorders abetted by a strong placebo effect. Studies with pain as the primary outcome commonly are subject to large placebo effects. The CTAF assessment observed that, in the non-blinded randomized controlled trials of ESWT, the placebo group usually reported minimal improvements, while the placebo group in the well blinded studies reported 30 to 50% improvements in pain scores. The CTAF assessment concluded, therefore, that high quality, double-blinded, randomized trials are the minimum standard of evidence (Tice, 2009).

The CTAF report stated that meta-analysis of the 19 randomized controlled trials of ESWT for plantar fasciitis illustrates this quite clearly (Tice, 2009). The CTAF assessment found significant variability in the quality of the randomized trials and in the interventions studied. However, only the quality of the studies was significantly associated with the magnitude of the benefit observed in the clinical trials. The CTAF report observed that fair to poor quality studies demonstrated benefit compared with sham or delayed therapy, but the trials were generally small, with inadequate blinding, poor allocation concealment, and differential loss to follow-up, which could have biased the study results in favor of ESWT. However, 2 of the 4 good quality studies found no evidence for benefit compared with sham ESWT. Furthermore, the CTAF report found strong evidence for publication bias in the available literature. The asymmetry of the funnel plot indicates that many small studies with negative results have been performed, but not published. Finally, CTAF found that many different variations of ESWT were tried in these trials -- no specific device or protocol was clearly superior to the others. The CTAF report stated that there may be a form of ESWT that effectively speeds healing of plantar fasciitis, but it remains to be defined. The literature does not clearly support a benefit of high energy compared with low energy ESWT nor is it clear that the use of anesthesia blocks the benefits of ESWT. "Until unequivocal benefit is consistently demonstrated in high quality clinical trials, ESWT should remain investigational" (Tice, 2009).

It is interesting to note that a randomized controlled study (n = 125; Porter and Shadbolt, 2005) reported that corticosteroid injection is more effective and multiple times more cost-effective than ESWT in the treatment of plantar fasciopathy that has been symptomatic for more than 6 weeks. In addition, a recent review on the use of ESWT for the treatment of orthopedic diseases (Trebinjac et al, 2005) found that results on the effectiveness of ESWT are controversial. Studies that have claimed therapeutic benefit did not fulfill scientific criteria and randomized controlled trials were not able to confirm significant improvement after treatment with ESWT.

An assessment by the National Institute for Health and Clinical Excellence (NICE, 2005) about ESWT for plantar fasciitis reached the following conclusion: "[c]urrent evidence on extracorporeal shockwave 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. Therefore, current evidence on efficacy does not appear adequate to support its use without special arrangements for consent, and for audit or research."
A systematic evidence review and metaanalysis for *BMC Musculoskeletal Disorders* (Thomson et al, 2005) reported that the results of the review did not support the use of ESWT for plantar heel pain in clinical practice. The authors reported that ESWT was effective for the treatment of plantar heel pain, but the effect size was small; when only high-quality trials were considered, this effect was not shown to be statistically significant.

The Canadian Agency for Drugs and Technologies in Health's report on ESWT for chronic plantar fasciitis (Ho, 2007) stated that "the lack of convergent findings from randomized trials of ESWT for chronic plantar fasciitis suggests uncertainty about its effectiveness. The evidence reviewed in this bulletin does not support the use of this technology for this condition."

A meta-analysis of ESWT for plantar fasciitis not responding to conservative therapy (2007) conducted by the CTAF (2007) concluded that the use of ESWT for the treatment of plantar fasciitis does not meet CTAF's technology assessment criteria. Meta-analysis of the 14 randomized controlled clinical trials of ESWT for plantar fasciitis identified significant variability in the quality of the randomized trials and in the interventions studied. The assessment found, however, that only the quality of the studies was significantly associated with the magnitude of the benefit observed in the clinical trials. The CTAF assessment found that fair to poor quality studies demonstrated benefit compared with sham or delayed therapy, but the trials were generally small, with inadequate blinding, poor allocation concealment, and differential loss to follow-up, which could have biased the study results in favor of ESWT. In contrast, 2 of the 3 good quality studies found no evidence for benefit compared with sham ESWT.

Tornese and co-workers (2008) compared 2 ESWT techniques for the treatment of painful subcalcaneal spur. A total of 45 subjects with a history of at least 6 months of heel pain were studied. Each subject received a 3-session ultrasound-guided ESWT (performed weekly). Perpendicular technique was used in group A (n = 22, mean age of 59.3 +/- 12 years) and tangential technique was used in group B (n = 23, mean age of 58.8 +/- 12.3 years). Mayo Clinical Scoring System was used to evaluate each subject before the treatment and at 2 and 8 months follow-up. Mayo Clinical Scoring System pre-treatment scores were homogeneous between the groups (group A = 55.2 +/- 18.7; group B = 53.5 +/- 20; p > 0.05). In both groups there was a significant (p < 0.05) increase in the Mayo Clinical Scoring System score at 2 months (group A = 83.9 +/- 13.7; group B = 80 +/- 15.8) and 8 months (group A = 90 +/- 10.5; group B = 90.2 +/- 8.7) follow-up. No significant differences were obtained comparing the Mayo Clinical Scoring System scores of the 2 groups at 2 and 8 months follow-up. The authors concluded that there was no difference between the 2 techniques of using ESWT. The tangential technique was found to be better-tolerated regarding treatment-induced pain, allowing higher energy dosages to be used. The drawbacks of this study were lack of a control group, small sample size, and a relatively short follow-up period.

In a randomized controlled trial, Gerdesmeyer and colleagues (2008) examined the effects of radial ESWT in the treatment of chronic recalcitrant plantar fasciitis. Three interventions of radial ESWT (0.16 mJ/mm(2); 2,000 impulses) compared with placebo were studied in 245 patients. Primary endpoints were changes in VAS composite score from baseline to 12 weeks’ follow-up, overall success rates,
and success rates of the single VAS scores (heel pain at first steps in the morning, during daily activities, during standardized pressure force). Secondary endpoints were single changes in VAS scores, success rates, Roles and Maudsley score, SF-36, and patients' and investigators' global judgment of effectiveness 12 weeks and 12 months after ESWT. Radial ESWT proved significantly superior to placebo with a reduction of the VAS composite score of 72.1% compared with 44.7% (p = 0.0220), and an overall success rate of 61.0% compared with 42.2% in the placebo group (P = .0020) at 12 weeks. Superiority was even more pronounced at 12 months, and all secondary outcome measures supported radial ESWT to be significantly superior to placebo (p < 0.025, 1-sided). No relevant side effects were observed. The authors concluded that radial ESWT significantly improves pain, function, and quality of life compared with placebo in patients with recalcitrant plantar fasciitis. The positive findings of this study need to be validated by further investigation.

Cryosurgery is also being studied for the treatment of plantar fasciitis. In a prospective study (Allen et al, 2007), 59 consecutive patients (61 heels), who had failed prior conservative therapy and were considered surgical candidates were treated with cryosurgery in an office setting. Patients were evaluated on an 11-point VAS administered pre-operatively and up to 1 year of follow-up. The mean pain rating (8.38) before cryosurgery (day 0) is statistically significant to the mean pain rating (1.26) at day 365 post-operatively. Pain decreased significantly after the procedure (analysis of variance, p < 0.0001). These results suggested that cryosurgery may be effective in treating patients with recalcitrant plantar fasciitis. However, it should be noted that this was an uncontrolled study with a small sample size. Its findings need to be validated by well-designed studies.

Niewald and associates (2008) stated that a lot of retrospective data concerning the effect of radiotherapy on plantar fasciitis is available in the literature. Nevertheless, a randomized proof of this effect is still missing. Thus, the GCGBD (German cooperative group on radiotherapy for benign diseases) of the DEGRO (German Society for Radiation Oncology) decided to start a randomized multicenter trial in order to find out if the effect of a conventional total dose is superior compared to that of a very low dose. In a prospective, controlled and randomized phase III trial, 2 radiotherapy schedules were compared: (i) standard arm -- total dose 6.0 Gy in single fractions of 1.0 Gy applied twice-weekly, and (ii) experimental arm -- total dose 0.6 Gy in single fractions of 0.1 Gy applied twice-weekly (acting as a placebo). Patients aged over 40 years who have been diagnosed clinically and radiologically to be suffering from plantar fasciitis for at least 6 months can be included. Former trauma, surgery or radiotherapy to the heel are not allowed nor are patients with a severe psychiatric disease or women during pregnancy and breast-feeding. According to the statistical power calculation, 100 patients have to be enrolled into each arm. After having obtaining a written informed consent a patient is randomized by the statistician to one of the arms mentioned above. After radiotherapy, patients are seen first every 6 weeks, then regularly up to 48 months after therapy; they additionally receive a questionnaire every 6 weeks after the follow-up examinations. The effect is measured using several target variables (scores): Calcaneodynia-score according to Rowe et al, SF-12 score, and VAS of pain. The most important endpoint is the pain relief 3 months after therapy. Patients with an inadequate result are offered a second radiotherapy series applying the standard dose (equally in both arms).
This trial protocol has been approved by the expert panel of the DEGRO as well as by the Ethics committee of the Saarland Physicians' Chamber.

Drilling and microfracture of the subchondral bone are techniques used to stimulate the intrinsic repair (fibro-cartilage) process for injured/defective articular cartilage. However, there is a lack of evidence regarding the effectiveness of drilling or microfracture in the treatment of plantar fasciitis.

In a multi-center randomized clinical trial, Cleland and colleagues (2009) compared the effectiveness of 2 different conservative management approaches in the treatment of plantar heel pain. Patients with a primary report of plantar heel pain underwent a standard evaluation and completed a number of patient self-report questionnaires, including the Lower Extremity Functional Scale (LEFS), the Foot and Ankle Ability Measure (FAAM), and the Numeric Pain Rating Scale (NPRS). Patients were randomly assigned to be treated with either an electrophysical agents and exercise (EPAX) or a manual physical therapy and exercise (MTEX) approach. Outcomes of interest were captured at baseline and at 4-week and 6-month follow-ups. The primary aim (effects of treatment on pain and disability) was examined with a mixed-model analysis of variance (ANOVA). The hypothesis of interest was the 2-way interaction (group by time). A total of 60 subjects (mean [SD] age, 48.4 [8.7] years) satisfied the eligibility criteria, agreed to participate, and were randomized into the EPAX (n = 30) or MTEX group (n = 30). The overall group-by-time interaction for the ANOVA was statistically significant for the LEFS (p = 0.002), FAAM (p = 0.005), and pain (p = 0.043). Between-group differences favored the MTEX group at both 4-week (difference in LEFS, 13.5; 95 % confidence interval [CI]: 6.3 to 20.8) and 6-month (9.9; 95 % CI: 1.2 to 18.6) follow-ups. The authors concluded that the results of this study provided evidence that MTEX is a superior management approach over an EPAX approach in the management of individuals with plantar heel pain at both the short- and long-term follow-ups.

Rompe et al (2010) tested the null hypothesis of no difference in the effectiveness of plantar fascia-specific stretching and shock-wave therapy for patients who had unilateral plantar fasciopathy for a maximum duration of 6 weeks and which had not been treated previously. A total of 102 patients with acute plantar fasciopathy were randomly assigned to perform an 8-week plantar fascia-specific stretching program (group I, n = 54) or to receive repetitive low-energy radial shock-wave therapy without local anesthesia, administered weekly for 3 weeks (group II, n = 48). All patients completed the 7-item pain subscale of the validated Foot Function Index and a patient-relevant outcome questionnaire. Patients were evaluated at baseline and at 2, 4, and 15 months after baseline. The primary outcome measures were a mean change in the Foot Function Index sum score at 2 months after baseline, a mean change in item 2 (pain during the first few steps of walking in the morning) on this index, and satisfaction with treatment. No difference in mean age, sex, weight, or duration of symptoms was found between the groups at baseline. At 2 months after baseline, the Foot Function Index sum score showed significantly greater changes for the patients managed with plantar fascia-specific stretching than for those managed with shock-wave therapy (p < 0.001), as well as individually for item 2 (p = 0.002). Thirty-five patients (65 %) in group I versus 14 patients (29 %) in group II were satisfied with the treatment (p < 0.001). These findings persisted at 4 months. At 15 months after baseline, no
significant between-group difference was measured. The authors concluded that a program of manual stretching exercises specific to the plantar fascia is superior to repetitive low-energy radial shock-wave therapy for the treatment of acute symptoms of proximal plantar fasciopathy.

In a pilot study, Dogramaci et al (2010) examined the clinical efficacy of intracorporeal pneumatic shock therapy (IPST) application for the treatment of chronic plantar fasciitis using a pneumatic lithotripter. A total of 50 patients with clinically and radiologically confirmed plantar fasciitis were randomly allocated to either an active (treatment) (n = 25) or inactive (placebo) (n = 25) group. Under local anesthesia and posterior tibial nerve block, a rigid probe was directly introduced into the calcaneal spur under fluoroscopic control; a standard protocol of 1,000 shocks was applied during a single session into the calcaneal spur. The main outcome measure was patients' subjective assessment of pain by means of a VAS and the Roles and Maudsley Score before the treatment and 6 months later. At the 6 months, the rate of successful outcomes (excellent + good results) in the treatment group (92 %) were significantly higher comparing to the control group (24 %) (p < 0.001). Heel pain measured 6 months after using the VAS were 2.04 +/- 1.67 in the treatment group and 7.16 +/- 1.57 in the control group as compared to 8.92 +/- 1.22 and 9.12 +/- 1.23, respectively before the commencement of the treatment. No complications attributable to the procedure such as rupture of the planter fascia, hematoma, or infection were observed during the study. The authors concluded that these findings showed that IPST is a safe and effective method in the treatment of patients with chronic plantar fasciitis not responding to conservative measures. It should be considered before surgical intervention when ESWT is not available for daily practice. Moreover, they stated that further evaluation of this novel treatment is necessary to understand the exact mechanism of action.

Peerbooms et al (2010) described the design of a multi-center randomized controlled trial to study the use of platelet rich plasma in the treatment of plantar fasciitis. The study population consists of 120 patients aged 18 years and older. Patients with chronic plantar fasciitis will be allocated randomly to have a steroid injection or an autologous platelet concentrate injections. Data will be collected before the procedure, 4, 8, 12, 26 weeks and 1 year after the procedure. The main outcome measures of this study are pain and function measured with questionnaires.

Cotchett et al (2011) described the design of a randomized controlled trial to evaluate the effectiveness of dry needling for plantar heel pain. A total of 80 community-dwelling men and woman aged over 18 years with plantar heel pain (who satisfy the inclusion and exclusion criteria) will be recruited. Eligible participants with plantar heel pain will be randomized to receive either 1 of 2 interventions, (i) real dry needling, or (ii) sham dry needling. The protocol (including needling details and treatment regimen) was formulated by general consensus (using the Delphi research method) using 30 experts worldwide that commonly use dry needling for plantar heel pain. Primary outcome measures will be the pain subscale of the Foot Health Status Questionnaire and "first step" pain as measured on a VAS. The secondary outcome measures will be health-related quality of life (assessed using the Short Form-36 questionnaire - Version Two) and depression, anxiety and stress (assessed using the Depression, Anxiety and
Stress Scale - short version). Primary outcome measures will be performed at baseline, 2, 4, 6 and 12 weeks and secondary outcome measures will be performed at baseline, 6 and 12 weeks. Data will be analyzed using the intention-to-treat principle. The authors concluded that this study is the first randomized controlled trial to evaluate the effectiveness of dry needling for plantar heel pain. The trial will be reported in accordance with the Consolidated Standards of Reporting Trials and the Standards for Reporting Interventions in Clinical Trials of Acupuncture guidelines. The findings from this trial will provide evidence for the effectiveness of trigger point dry needling for plantar heel pain.

Zhang et al (2011) examine the efficacy of botulinum toxin type A (BoNTA) in reducing chronic musculoskeletal pain. Studies for inclusion in this report were identified using MEDLINE, EMBASE, PUBMED, Cochrane Central Register of Controlled Trials, CINAHL, and reference lists of relevant articles. Studies were considered eligible for inclusion if they were randomized controlled trials (RCTs), evaluating the efficacy of BoNTA injections in pain reduction. All studies were assessed and data were abstracted independently by paired reviewers. The outcome measures were baseline and final pain scores as assessed by the patients. The internal validity of trials was assessed with the Jadad scale. Disagreements were resolved through discussions. A total of 21 studies were included in the systematic review and 15 of them were included in the final meta-analysis. There was a total of 706 patients in the meta-analysis, represented from trials of plantar fasciitis (n = 1), tennis elbow (n = 2), shoulder pain (n = 1), whiplash (n = 3), and myofascial pain (n = 8). Overall, there was a small to moderate pain reduction among BoNTA patients when compared to control (SMD = -0.27, 95% CI: -0.44 to -0.11). When the results were analyzed in subgroups, only tennis elbow (SMD = -0.44, 95% CI: -0.86 to -0.01) and plantar fasciitis (SMD = -1.04, 95% CI: -1.68 to -0.40) demonstrated significant pain relief. Although not in the meta-analysis, 1 back pain study also demonstrated positive results for BoNTA. Lastly, BoNTA was effective when used at greater than or equal to 25 units per anatomical site or after a period greater than or equal to 5 weeks. In this meta-analysis, BoNTA had a small to moderate analgesic effect in chronic musculoskeletal pain conditions. It was particularly effective in plantar fasciitis, tennis elbow, and back pain, but not in whiplash or shoulder pain patients. However, more evidence is required before definitive conclusions can be drawn. On the other hand, there is convincing evidence that BoNTA lacks strong analgesic effects in patients with myofascial pain syndrome.

Diaz-Llopis et al (2012) examined the effectiveness of BoNTA in chronic plantar fasciitis compared to the local injection of a corticosteroid plus local anesthetic. Patients with a clinical diagnosis of plantar fasciitis made at least 6 months earlier were selected to enter a randomized, single-blind study of treatment with injections of botulinum toxin type A or corticosteroid. There were 28 patients in each treatment group. Patients were evaluated at 1 month using the Foot Health Square Questionnaire and those with no clinical response subsequently received a 2nd injection with the drug of the other arm of the study, creating 2 new treatment groups. Re-evaluation was performed at 6 months. One month after injection there was a clear clinical improvement in both treatment groups but it was greater in the botulinum toxin group, with a significant difference for the pain item (p = 0.069), though not in other items. At 6 months, patients treated with botulinum toxin type A had continued to improve in all items, whereas the corticosteroid
group lost part of the improvement achieved at 1 month (improvement with botulinum toxin versus corticosteroid: pain 19.10/-6.84 (p = 0.001), function 16.00/-8.80 (p < 0.001), footwear 13.48/-7.95 (p = 0.004), self-perceived foot health 25.44/-5.41 (p < 0.001). The authors concluded that BoNTA should be considered for the treatment of chronic plantar fasciitis in view of the improvement found at 1 month, and particularly at 6 months, when this treatment clearly has better results than corticosteroid injections. They stated that further studies with larger samples are necessary to confirm these results.

In a double-blind, multi-center, randomized, placebo-controlled study, Brook et al (2012) evaluated the clinical value of pulsed radiofrequency electromagnetic field (PREF) therapy as a potential novel treatment of plantar fasciitis. A small, wearable, extended-use PRFE device was employed in this study. A total of 70 subjects diagnosed with plantar fasciitis were enrolled in the present study. The subjects were randomly assigned a placebo or active PRFE device. Subjects were instructed to wear the PRFE device over-night, record their morning and evening pain using a 0- to 10-point VAS, and log any medication use. The primary outcome measure for the present study was morning pain, a hallmark of plantar fasciitis. The study group using the active PRFE device showed progressive decline in morning pain. The day 7 AM-VAS score was 40 % lower than the day 1 AM-VAS score. The control group, in comparison, showed a 7 % decline. A significantly different decline was demonstrated between the 2 groups (p = 0.03). The PM-VAS scores declined by 30 % in the study group compared to 19 % in the control group, although the difference was non-significant. Medication use in the study group also showed a trend downward, but the use in the control group remained consistent with the day 1 levels. The authors concluded that PRFE therapy worn on a nightly basis appears to offer a simple, drug-free, non-invasive therapy to reduce the pain associated with plantar fasciitis. The findings of this study need to be validated by further investigations especially since there were no significant differences in VAS score between the study and control groups.

The National Institute for Health and Clinical Excellence assessment on “Autologous blood injection for plantar fasciitis” (NICE, 2013) concluded that “The evidence on autologous blood injection for plantar fasciitis raises no major safety concerns. The evidence on efficacy is inadequate in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research . . . . NICE encourages further research comparing autologous blood injection (with or without techniques to produce platelet-rich plasma) against established treatments for managing plantar fasciitis. Trials should clearly describe patient selection, including duration of symptoms and any prior treatments. Outcomes should include specific measures of pain and function”.

Morris et al (2013) examined the effect of Kinesio Tex tape (KTT) from RCTs in the management of clinical conditions. A systematic literature search of CINAHL; MEDLINE; OVID; AMED; SCIENCE DIRECT; PEDRO; http://www.internurse.com/; SPORT DISCUS; BRITISH NURSING INDEX; http://www.kinesiotaping.co.uk;www.kinesiotaping.com/; COCHRANE CENTRAL REGISTER OF CLINICAL TRIALS; and PROQUEST was performed up to April 2012. The risk of bias and quality of evidence grading was performed using the Cochrane collaboration methodology. A total of 8 RCTs met the full
inclusion/exclusion criteria; 6 of these included patients with musculoskeletal conditions; 1 included patients with breast-cancer-related lymphedema; and 1 included stroke patients with muscle spasticity. Six studies included a sham or usual care tape/bandage group. There was limited to moderate evidence that KTT is no more clinically effective than sham or usual care tape/bandage. There was limited evidence from 1 moderate quality RCT that KTT in conjunction with physiotherapy was clinically beneficial for plantar fasciitis related pain in the short-term; however, there were serious questions around the internal validity of this RCT. The authors concluded that there currently exists insufficient evidence to support the use of KTT over other modalities in clinical practice.

Zelen et al (2013) reported the results of a feasibility study examining the effectiveness of micronized dehydrated human amniotic/chorionic membrane (mDHACM) injection as a treatment for chronic refractory plantar fasciitis. An institutional review board-approved, prospective, randomized, single-center clinical trial was performed. A total of 45 patients were randomized to receive injection of 2 cc 0.5 % Marcaine plain, then either 1.25 cc saline (controls), 0.5 cc mDHACM, or 1.25 cc mDHACM. Follow-up visits occurred over 8 weeks to measure function, pain, and functional health and well-being. Significant improvement in plantar fasciitis symptoms was observed in patients receiving 0.5 cc or 1.25 cc mDHACM versus controls within 1 week of treatment and throughout the study period. At 1 week, AOFAS Hindfoot scores increased by a mean of 2.2 ± 17.4 points for controls versus 38.7 ± 11.4 points for those receiving 0.5 cc mDHACM (p < 0.001) and 33.7 ± 14.0 points for those receiving 1.25 cc mDHACM (p < 0.001). By week 8 AOFAS Hindfoot scores increased by a mean of 12.9 ± 16.9 points for controls versus 51.6 ± 10.1 and 53.3 ± 9.4 for those receiving 0.5 cc and 1.25 cc mDHACM, respectively (both p < 0.001). No significant difference in treatment response was observed in patients receiving 0.5 cc versus 1.25 cc mDHACM. The authors concluded that in patients with refractory plantar fasciitis, mDHACM is a viable treatment option. Moreover they stated that larger studies are needed to confirm these findings.

In a meta-analysis, Yin et al (2014) examined the effectiveness of ESWT and provided clinicians with an evidence base for their clinical decision-making. PubMed, MEDLINE, Embase, Cochrane Central Register of Controlled Trials, and Evidence-Based Medicine Reviews served as data sources. All randomized or quasi-randomized controlled trials of ESWT for chronic recalcitrant plantar fasciitis were searched. Searching identified 108 potentially relevant articles; of these, 7 studies with 550 participants met inclusion criteria. Number of patients, population, body mass index (BMI), duration of symptoms, adverse effects, blinding method, and details of shockwave therapy were extracted. For intervention success rate, ESWT of low intensity was more effective than control treatment of low intensity. For pain relief, the pooled data showed a significant difference between the ESWT and control groups. For function, only low-intensity ESWT was significantly superior over the control treatment. The authors concluded that the effectiveness of low-intensity ESWT is worthy of recognition. The short-term pain relief and functional outcomes of this treatment are satisfactory. However, they noted that owing to the lack of a long-term follow-up, its long-term effectiveness remains unknown.
In a systematic review, Sandrey (2014) evaluated the literature to critically consider the effects of growth factors delivered through autologous whole-blood and platelet-rich-plasma (PRP) injections in managing wrist-flexor and-extensor tendinopathies, plantar fasciopathy, and patellar tendinopathy. The primary question was, according to the published literature, is there sufficient evidence to support the use of growth factors delivered through autologous whole-blood and PRP injections for chronic tendinopathy? The authors performed a comprehensive, systematic literature search in October 2009 using PubMed, MEDLINE, EMBASE, CINAHL, and the Cochrane library without time limits. The following key words were used in different combinations: tendinopathy, tendinosis, tendinitis, tendons, tennis elbow, plantar fasciitis, platelet rich plasma, platelet transfusion, and autologous blood or injection. The search was limited to human studies in English. All bibliographies from the initial literature search were also viewed to identify additional relevant studies. Studies were eligible based on the following criteria: (i) Articles were suitable (inclusion criteria) if the participants had been clinically diagnosed as having chronic tendinopathy; (ii) the design had to be a prospective clinical study, RCT, non-RCT, or prospective case series; (iii) a well-described intervention in the form of a growth factor injection with either PRP or autologous whole blood was used; and (iv) the outcome was reported in terms of pain or function (or both). All titles and abstracts were assessed by 2 researchers, and all relevant articles were obtained. Two researchers independently read the full text of each article to determine if it met the inclusion criteria. If opinions differed on suitability, a third reviewer was consulted to reach consensus. The data extracted included number of participants, study design, inclusion criteria, intervention, control group, primary outcome measures (pain using a visual analog or ordinal scale or function), time of follow-up, and outcomes for intervention and control group (percentage improvement) using a standardized data-extraction form. Function was evaluated in 9 of the 11 studies using (i) the Nirschl scale (elbow function) or the modified Mayo score for wrist flexors and extensors, (ii) the Victorian Institute of Sports Assessment-Patella score, a validated outcome measure for patellar tendinopathy, or the Tegner score for patellar tendinopathy, and (iii) the rear-foot score from the American Orthopaedic Foot and Ankle Scale for plantar fasciopathy. The Physiotherapy Evidence Database (PEDro) scale contains 11 items; items 2 to 11 receive 1 point each for a yes response. Reliability is sufficient (0.68) for the PEDro scale to be used to assess physiotherapy trials. A score of 6 or higher on the PEDro scale is considered a high-quality study; below 6 is considered a low-quality study. The PEDro score results determined the quality of the RCT, non-RCT, or prospective case series (greater than or equal to 6 or less than 6). A qualitative analysis was used with 5 levels of evidence (strong, moderate, limited, conflicting, or no evidence) to determine recommendations for the use of the intervention. The number of high-quality or low-quality RCT or non-randomized clinical trial studies with consistent or inconsistent results determined the level of evidence (1 to 5). Using the specific search criteria, the authors identified 418 potential sources. After screening of the title or abstract (or both), they excluded 405 sources, which left 13 studies. After viewing the full text, they excluded 2 additional sources (a case report and a study in which the outcome measure was remission of symptoms and not pain or function), leaving 11 studies for analysis. Six of the 11 studies were characterized by an observational, non-controlled design; the remaining 5 studies were
controlled clinical trials, 2 of which had proper randomization. The mean number of participants included in the studies was 40.5 (range of 20 to 100). Three of the studies were on "tennis elbow", 1 on "golfer's elbow", 1 on wrist extensor or flexor tendinopathy, 3 on plantar fasciopathy, and 3 on chronic patellar tendinopathy. Based on the information reported, there was no standardization of frequency or method of growth factor injection treatment or of preparation of the volume, and an optimal mixture was not described. Autologous whole-blood injections were used in 8 studies; in 5 studies, the autologous whole-blood injection was combined with a local anesthetic. In contrast, a local anesthetic was used in only 1 of the 3 PRP injection studies. The authors of the other 2 studies did not report whether a local anesthetic was used. The number of autologous whole-blood and PRP injections varied, ranging from 1 to 3. The centrifuging process was single or double for the PRP injections. In 2 studies, calcium was added to activate the platelets. A visual analog or ordinal pain scale was used in 10 of the 11 studies. Function was evaluated in 9 of the 11 studies using (i) the Nirschl scale in 4 elbow studies or the modified Mayo score at baseline in 1 elbow study, (ii) the Victorian Institute of Sports Assessment-Patella score for 1 study and the Tegner score for 2 of the patellar tendinopathy studies, and (iii) the rear-foot score of the American Orthopaedic Foot and Ankle Scale for 1 plantar fasciopathy study. Only 1 study used an appropriate, disease-specific, validated tendinopathy measure (Victorian Institute of Sports Assessment-Patella). All intervention groups reported a significant improvement in pain or function score (or both), with a mean improvement of 66% over a mean follow-up of 9.4 months. The control groups in these studies also showed a mean improvement of 57%. None of the pain benefits among the intervention groups were greater than those for the control group at final follow-up. In 4 of the studies, the control group and the autologous growth factor injection group had similar results in pain or function or both, whereas in 2 studies, the control group had greater relief in pain than the injection group. Eleven studies were assessed using the PEDro scale. The PEDro scores for these studies ranged from 1 to 7, with an average score of 3.4. Only 3 studies had PEDro scores of ≥6 and were considered high quality. The 3 high-quality plantar fasciopathy studies used autologous growth factor injections but did not show a significant improvement over the control group. One of the studies that showed no beneficial effect for the autologous growth factor injections was compared with corticosteroids. Compared with other treatments, level 1 (strong) evidence demonstrated that autologous growth factor injections did not improve pain or function in plantar fasciopathy. The PRP injection results were based on 3 low-quality studies, 2 for the patellar tendon and 1 for the wrist flexors-extensors; level 3 (limited) evidence suggested that PRP injections improve pain or function. The authors concluded that strong evidence indicated that autologous growth factor injections do not improve plantar fasciopathy pain or function when combined with anesthetic agents or when compared with corticosteroid injections, dry needling, or exercise therapy treatments. Furthermore, limited evidence suggested that PRP injections are beneficial. Except for 2 high-quality RCT studies, the rest were methodologically flawed. They stated that additional studies should be conducted using proper control groups, randomization, blinding, and validated disability outcome measures for pain and function. Until then, the results remain speculative because autologous whole-blood and PRP injection treatments are not standardized.
Jastifer et al (2014) stated that a newly emerging technology, low-level laser therapy (LLLT), has demonstrated promising results for the treatment of acute and chronic pain. In a prospective study examining the effects of LLLT for the treatment of chronic plantar fasciitis, a total of 30 patients were administered LLLT and completed 12 months of follow-up. Patients were treated twice-weekly for 3 weeks for a total of 6 treatments and were evaluated at baseline, 2 weeks post-procedure, and 6 and 12 months post-procedure. Patients completed the VAS and Foot Function Index (FFI) at study follow-up periods. Patients demonstrated a mean improvement in heel pain VAS from 67.8 out of 100 at baseline to 6.9 out of 100 at the 12-month follow-up period. Total FFI score improved from a mean of 106.2 at baseline to 32.3 at 12 months post-procedure. The authors concluded that although further studies are warranted, this study showed that LLLT is a promising treatment of chronic plantar fasciitis.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:
29893 Endoscopic plantar fasciotomy

CPT codes not covered for indications listed in the CPB:
0019T Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy
0232T Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed
20552 Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)
20553 Injection(s); single or multiple trigger point(s), 3 or more muscle(s)
28890 Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia

64642 - 64645 Chemodenervation of one extremity
77401 - 77417 Radiation treatment delivery

Other CPT codes related to the CPB:
28008 Fasciotomy, foot and/or toe
28060 Fasciectomy, plantar fascia; partial (separate procedure)
28062 radical (separate procedure)
Division of plantar fascia and muscle (eg, Steindler stripping) (separate procedure)

**HCPCS codes not covered for indications listed in the CPB:**

- E0761 Non-thermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device
- E0769 Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
- G6001 - G6014 Radiation treatment delivery
- J0585 Injection, onabotulinumtoxin A, 1 unit
- J0586 Injection, abobotulinumtoxin A, 5 units
- J0587 Injection, rimabotulinumtoxin B, 100 units
- J0588 Injection, incobotulinumtoxin A, 1 unit
- P9020 Platelet rich plasma, each unit

**Other HCPCS codes related to the CPB:**

- A4570 Splint
- L3000 - L3265 Orthopedic shoes
- L3300 - L3649 Shoe modifications
- L4350 - L4398 Splint, ankle, foot, leg
- S8451 Splint, prefabricated, wrist or ankle

**ICD-9 codes covered if selection criteria are met:**

- 726.73 Calcaneal spur
- 728.71 Plantar fascial fibromatosis

**Kinesio Tex taping:**

No specific code

**Micronized dehydrated amniotic/chorionic membrane allograft:**

No specific code

The above policy is based on the following references:


