Plantar Fasciitis Treatments

Table of Contents
Coverage Policy ................................................... 1
Overview .............................................................. 2
General Background ............................................ 2
Coding/Billing Information ................................. 14
References ......................................................... 15

Related Coverage Resources
Acupuncture
Autologous Platelet-Derived Growth Factors (Platelet-Rich Plasma [PRP])
Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions
Lower Limb Orthoses and Shoes
Low-Level Laser and High-Power Laser Therapy
Peripheral Nerve Destruction for Pain Conditions
Physical Therapy
Stretch Devices for Joint Stiffness and Contractures
Tissue-Engineered Skin Substitutes

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document (Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document) may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Coverage Policy

For information on the use of splints/foot orthoses associated with plantar fasciitis, refer to the Cigna Coverage Policy Lower Limb Orthoses and Shoes.

Each of the following interventions is considered experimental, investigational or unproven for the treatment of plantar fasciitis:

- autologous platelet-derived growth factors
- coblation® (e.g., Topaz™)
- electron-generating devices
- extracorporeal shock wave therapy (ESWT), including extracorporeal pulse activation therapy (EPAT®)
- intracorporeal pneumatic shock therapy (IPST)
- laser therapy
• low-load prolonged-duration stretch (LLPS) devices (e.g., Dynasplint System®, Ultraflex, Pro-glide™ Dynamic ROM, Advance Dynamic ROM®)
• microwave diathermy
• percutaneous ultrasonic ablation (e.g., Tenex Health TX®)
• pulsed radiofrequency electromagnetic field (PREF) therapy
• radiotherapy
• stereotactic radiofrequency thermal lesioning
• trigger-point needling and infiltration of the proximal medial gastrocnemius muscle

Overview

This Coverage Policy addresses various minimally invasive treatments for plantar fasciitis.

General Background

Plantar fasciitis is an overuse injury resulting in inflammation of the plantar fascia, which connects the heel to the toes. It is a common cause of heel pain in adults. Symptoms usually start gradually with mild pain at the heel, pain after exercise and pain with standing first thing in the morning. On physical examination, firm pressure will elicit a tender spot over the medial tubercle of the calcaneus. Risk factors for plantar fasciitis may include: obesity, age, being female, limited dorsiflexion of the ankle joint, prolonged weight bearing, and an increase in the amount of walking or running. Heel spurs are not necessarily associated with plantar fasciitis; heel spurs may be found in asymptomatic patients. Early treatment generally results in a shorter duration of symptoms.

First-Line Treatment

The mainstay of nonsurgical treatment and the standard of care for initial treatment is a program of stretching exercises, ice, activity modification, weight loss in overweight patients, recommendations for appropriate footwear, arch taping, nonsteroidal anti-inflammatory medications and shock-absorbing shoe inserts or orthoses. Prefabricated orthoses have been shown to be adequate for the majority of patients with various heel pain syndromes.

Iontophoresis is also an accepted noninvasive therapy for plantar fasciitis. Iontophoresis is the use of electric impulses from a low-voltage galvanic current stimulation unit to drive topical corticosteroids into soft tissue structures. The effectiveness of iontophoresis combined with traditional modalities has been demonstrated in randomized controlled trials (RCTs) (Osborne and Allison, 2006; Gudeman, et al., 1997). Iontophoresis may be tried as part of a first-line physical therapy program.

Second-Line Treatment

In the event early treatment fails, night splints, steroidal anti-inflammatory injections or a walking cast are the next level of the standard of care.

A night dorsiflexion splint allows passive stretching of the calf and the plantar fascia during sleep. In theory, it also allows healing to occur while the plantar fascia is in an elongated position, thereby creating less tension with the first step in the morning. A night splint can be molded from plaster or fiberglass casting material or may be a prefabricated plastic brace (Young, et al., 2001). A number of studies support the efficacy of night splints (Roos, et al., 2006; Crawford and Thomson, 2003; Barry, et al., 2002; Berlet, et al., 2002; Powell, 1998).

Evidence on the effectiveness of steroid injections in reducing pain in patients with plantar fasciitis includes a systematic review of randomized and quasi-randomized controlled trials (David, et al., 2017; Crawford and Thomson, 2003). In general, the studies that compared steroid injections with placebo substances showed initial significant improvement; however, studies that included follow-up after one month showed no difference in outcome at that time. This suggests that the effectiveness of steroid injections is short-term. Risks of steroid injection into the heel include rupture of the plantar fascia and fat pad atrophy.

The use of a short-leg walking cast for several weeks is a standard of care as a final conservative step in the treatment of plantar fasciitis.
Surgical Intervention
Surgical intervention should be considered only for intractable pain which has not responded to 6–12 months of proper conservative treatment. Plantar fasciotomy can be conducted using open or endoscopic techniques. Endoscopic plantar fasciotomy is a less invasive technique requiring an incision of less than one-half inch in length and utilizing an arthroscope to visualize and release the fascia. It has been proposed as an improvement over open plantar fasciotomy, resulting in less trauma and improved recovery times. There are a substantial number of retrospective studies supporting the use of endoscopic plantar fasciotomy. Based on the large number of reports of relief of heel pain from a series of nonrandomized trials, endoscopic plantar fasciotomy appears effective in the treatment of plantar fasciitis (Urovitz, et al., 2008, Boyle and Slater, 2003; O’Malley, et al., 2000; Lundeen, et al., 2000; Benton-Weil, et al., 1998).

Unproven Therapies for Plantar Fasciitis
There are many therapies that have been suggested for treatment of plantar fasciitis that are not proven in the literature and not accepted as standard of care.

Autologous Platelet-Derived Growth Factors: Autologous platelet-derived growth factors (APDGF) also referred to as autologous platelet concentrate, platelet-rich plasma (PRP), platelet-rich concentrate, have been proposed for the treatment of multiple conditions to enhance healing. In addition to hard and soft tissue wound healing, purported benefits of this treatment include reduced inflammation, decreased blood loss, and reduced postoperative narcotic requirements. Several centrifuges are designed to concentrate platelet-enriched plasma from small amounts of autologous blood at the point of care. The platelet concentrate can then combined with other substances to form a gel for patient application. Outcomes have been documented using APDGF injection for a wide range of indications, including musculoskeletal conditions. APDGF injection has been evaluated as a treatment for plantar fasciitis in few randomized controlled trials (RCTs) showing no significant improvement when compared to a control group.

Yang et al. (2017) performed a meta-analysis (n=9 RCTs/430 patients) to evaluate the current evidence concerning the safety and efficacy of PRP as a treatment for plantar fasciitis compared to steroid treatments. RCTs or prospective cohort studies that compared PRP to a control (e.g., steroid treatment) in patients diagnosed with plantar fasciitis were included. Studies were excluded in which subjects had a traumatic disease, a history of surgical interventions, or systemic disorders such as rheumatoid arthritis. Outcome measurements included the visual analogue scale (VAS), the Foot and Ankle Disability Index (FADI), American Orthopedic Foot and Ankle Society (AOFAS) scale, and the Roles and Maudsley Score (RMS). Follow-up times were divided into short periods (two–four weeks), intermediate periods (four–24 weeks), and long periods (≥24 weeks through 48 weeks). No significant differences in the VAS scores were observed between the two groups in the short term and intermediate term, however, PRP demonstrated better long-term efficacy than steroid treatments (p=0.03). No significant differences in the FADI and AOFAS Scale were observed between the groups after 12 weeks. Similarly no significant differences in the RMS were between groups was found after six months. Limitations of this meta-analysis include small sample size and heterogeneity between studies. Additional well-designed, long term studies are needed to establish the role of PRP as a treatment for plantar fasciitis.

Hayes (2018) conducted a comparative effectiveness review on PRP for the treatment of Achilles tendon rupture (ATR) and plantar fasciitis. The review included 13 randomized controlled trials—three studies for the treatment of ATR, two studies using PRP during ATR surgery, and eight studies for the treatment of plantar fasciitis. Comparators included: no PRP; conventional treatment; corticosteroids (CS); endoscopic plantar fasciotomy (EPF); extracorporeal shockwave therapy (ESWT); high-volume injection of saline between the tendon and the tendon sheath (HVI); low dose radiation (LDR); saline; and stromal vascular fraction (SVF). Follow-ups ranged from 16 weeks to 42 months. The use of PRP during surgical treatment of ATR did not yield better functional outcomes compared to surgery without PRP. The evidence for use of PRP in AT was limited and did not support PRP over saline. Regarding PRP for the treatment of plantar fasciitis (PF), three randomized controlled trials suggested that PRP was associated with better functional improvement and pain relief at 6–24 months compared with CS. However, differences between PRP and CS were not found in another study with shorter follow-ups. Data for PRP compared with other PF treatments (i.e., conventional treatment, ESWT, EPF, or LDR) were limited and reported no significant differences in functional or pain outcomes. No serious PRP adverse events were reported. Overall, the quality of the evidence was low due to the limited number of studies and lack
of comparison to established treatment modalities. There is insufficient evidence to establish patient selection
criteria for the use of PRP in the treatment of conditions of the Achilles tendon and plantar fascia.

Monto (2014) published results of a single-blinded, prospective, randomized, longitudinal study (n=40) of patients
with chronic plantar fasciitis to compare the effectiveness of autologous PRP and corticosteroid injection.
Chronic refractory plantar fasciitis was defined as those patients who had experienced at least four months of
heel pain despite a standardized trial of conservative treatment including rest, physical therapy. Group one
received a single ultrasound-guided injection of cortisone, and group two was treated with a single ultrasound-
guided injection of autologous PRP. Follow-up occurred through 24 months following injection treatment. The
difference between the post-treatment pain scoring results of the cortisone and PRP groups was clinically
significant in favor of PRP (p=0.001) at all follow-up evaluations. An acknowledged primary limitation of this study
is the single-blinded design. Study results suggest that PRP may provide improved pain control compared to
cortisone injection. However larger well-designed, controlled studies are needed to validate this finding.

A comparative study (n=60) by Akşahin et al. (2012) evaluated patients with chronic plantar fasciitis treated with
corticosteroid injection versus platelet rich plasma injection. Satisfactory results were achieved with both
treatment methods. There were no significant differences in pain scores at three weeks and six months following
injections (p>0.05). Study limitations include small patient population, short-term follow-up, and lack of
randomized design.

de Vos et al. (2010) conducted a systematic review (n=11 studies) of the evidence on autologous growth factor
injections of whole blood or platelet-rich plasma for chronic tendinopathy. Chronic tendinopathy in this study
included wrist extensors, flexors, plantar fasciopathy and patellar tendinopathy. There were six observational,
non-controlled studies and five controlled clinical trials, two of which were determined to have appropriate
randomization. The mean number of subjects was 40, with a range 20–100. Patients with chronic plantar
fasciopathy were treated in three studies (n=218 subjects). Outcome measures included measurements of pain
and function. The review found strong evidence that the use of injections with autologous whole blood should not
be recommended. No high-quality studies were found on platelet-rich plasma treatment.

Lee and Ahmad (2007) conducted a prospective, randomized, controlled, observer-blinded study (n=64) to
compare the efficacy of intrallesional autologous blood with corticosteroid injection for plantar fasciitis. Data were
complete for 61 patients, 30 patients in the autologous blood group and 31 patients in the corticosteroid group.
Over the six-month follow-up period, a significant reduction in pain levels was noted in both groups (p<0.0001).
At six months after treatment, patients who had received the corticosteroid injection had lower average levels of
pain than those who had received the autologous blood injection, but the difference was not significant
(p=0.094). Acknowledged limitations of this study included its short-term follow-up and the lack of a control group
that would show the natural history of the disease without intervention.

Kiter et al. (2006) evaluated the efficacy of autologous platelet injection for plantar fasciitis in an RCT (n=45). The
45 patients were treated for heel pain using either the peppering technique (n=15), autologous blood injection
(n=15) or corticosteroid injection (n=15). In the peppering technique group, after infiltration of one milliliter (ml) of
2% prilocaine, the needle was inserted, withdrawn and redirected 10–15 times without emerging from the skin.
At six-month follow-up, clinical improvement was evaluated using a VAS. Improvements in VAS scores were
reported to be 68%, 68% and 65% for the peppering technique, autologous blood injection and corticosteroid
injection groups, respectively. Larger, well-designed RCTs are needed to further define the role of autologous
blood injection in the treatment for plantar fasciitis.

There is insufficient evidence in the published peer-reviewed medical literature to support the use of autologous
blood injection for the treatment of plantar fasciitis.

Coblation®: Coblation, also referred to as cold or controlled ablation, has been proposed as a therapy for plantar
fasciitis. Coblation bipolar technology uses radiofrequency energy to excite the electrolytes in a conductive
medium, such as saline solution, creating precisely focused plasma. The plasma particles are then able to break
molecular bonds within tissue, causing the tissue to dissolve at relatively low temperatures. It is theorized that
this plasma radiofrequency-based microsurgery may promote an angiogenic healing response. Because the
current does not pass directly through tissue, there is minimal thermal injury to any surrounding tissues.
Coblation technology can be delivered via a number of different wands, hand pieces and other electrosurgical systems. The ArthroCare Topaz™ MicroDebrider™ (ArthroCare Corporation, Sunnyvale, CA) was granted marketing approval by the FDA via the 510(k) process on March 5, 2006, because it is considered to be substantially equivalent to another device already on the market. The 510(k) summary stated that the orthopedic system is substantially equivalent to the ArthroCare Topaz™ ArthroWands. Under the FDA 510(k) approval process, the manufacturer is not required to supply to the FDA evidence of the effectiveness of the Topaz MicroDebrider prior to marketing the device. According to the FDA, the Topaz MicroDebrider is indicated for debridement, resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic and arthroscopic procedures.

Studies in the published peer-reviewed literature assessing the effectiveness of coblation-based fasciotomy for relieving pain associated with plantar fasciitis are lacking. Therefore, coblation technology for this indication is unproven at present.

Electron-Generating Devices: There is no evidence to support the use of electron generating devices in the treatment of plantar fasciitis (Crawford and Thomson, 2003).

Extracorporeal Shock Wave Therapy (ESWT): ESWT, also called orthotripsy, is a noninvasive treatment that involves delivery of 1000–3000 shock waves to the painful heel region, and has been introduced as an alternative to surgery for patients with chronic plantar fasciitis that has not responded to medical therapy. The mechanism by which ESWT might work to relieve pain associated with plantar fasciitis is unknown. It has been hypothesized that the shock waves may reduce transmission of pain signals from sensory nerves in the plantar fascia, and/or may stimulate healing (Huang, et al., 2000).

The two types of ESWT are focused and radial. Focused ESWT directs shock waves at a targeted area with high tissue penetration where it is proposed to stimulate healing and disrupts pain signals. The shock waves may be generated using electrohydraulic, electromagnetic or piezoelectric technology (Hayes, 2016a; reviewed 2018). The difference between the three methods of generation is the time at which the shockwave forms (Roerdink, et al., 2017).

Radial ESWT uses pneumatic (compressed air) devices to deliver radial shock waves to a wider area than focused ESWT at a relatively low energy level (Hayes, 2016b; reviewed 2017). This generates stress waves in the applicator that transmit pressure waves (radial shock waves) non-invasively into tissue. Since the waves generated by radial ESWT are not true shock waves, the technology is also referred to as radial pressure wave therapy or extracorporeal pulse activation therapy (EPAT) (Császár, et al., 2015). However, published literature continues to refer to radically generated wave therapy as radial ESWT.

U.S. Food and Drug Administration (FDA): A number of ESWT devices for the treatment of plantar fasciitis are currently approved by the U.S. FDA including the OssaTron® lithotripter (HealthTronics, Marietta, GA); the Epos™ Ultra high-energy device (Dornier Medical Systems, Germering, Germany); the Orthospec™ (Medispec, Ltd, Germantown, MD); the Orbasone Pain Relief System (Orthometrix, Inc., White Plains, NY); and the EMS Swiss Dolorclast® (Electro Medical Systems [EMS], North Attleboro, MA).

Literature Review: The safety and effectiveness of ESWT for the treatment of plantar fasciitis have been evaluated in technology assessments, meta-analyses, and randomized controlled trials (RCTs). A number of RCTs (n=45–272) have compared ESWT to placebo for the treatment of plantar fasciitis with conflicting results. A greater reduction in heel pain for patients treated with ESWT has been reported in some studies (Ibrahim, et al., 2010; Gerdesmeyer, et al., 2008; Kudo, et al., 2006; Malay, et al., 2006; Theodore, et al., 2004; Rompe, et al., 2003), while similar improvement rates for both treatment and placebo groups have been reported in other studies (Haake, et al., 2003; Buchbinder, et al., 2002). An RCT (n=32) by Greve et al. (2009) compared radial shockwave treatment (n=16) and conventional physiotherapy (n=16) for plantar fasciitis and found ESWT to be no more effective than conventional physiotherapy three months after treatment. An RCT (n=149) by Wang et al. (2007) found that patients who received ESWT showed significantly better pain and function scores compared to those who received conservative treatment (p<0.001). In general, these studies have limitations such as small sample sizes and short-term follow-up that limit the generalizability of their results.
Lai et al. (2018) published the results of a prospective randomized controlled trial which evaluated and compared the therapeutic effects of ESWT and corticosteroid injections (CSI) in patients with chronic plantar fasciitis. The study also examined the correlation between plantar fascia thickness changes and clinical outcomes. Patients were included if they had more than two months without an injection and had been treated with conservative treatment for one month, without improvement before proceeding to ESWT or CSI treatment. Patients (n=110) were randomly assigned to receive ESWT (n=55) or CSI (n=55). The outcomes measured were a decrease in pain over a 12 week period and an increase in plantar fascia thickness. Outcomes were measured before treatment and at the fourth and 12th week following treatment using the visual analog scale (VAS), 100-points scoring system and ultrasound. Thirteen subjects were lost to follow-up and the outcomes were reported on the patients (n=97) that completed the study (n=47/ESWT group; n=50/CSI group). The VAS of patients that received ESWT was lower than those who received corticosteroid injection at the fourth and 12th week (p=0.001 and p<0.001 respectively). The 100-points scoring system indicated that the pain level of patients with ESWT was significantly lower than those with CSI at the 12th week (p<0.001). The analysis performed comparing changes in plantar fascia thickness to clinical outcomes found that the increase in the thickness of the plantar fascia at the fourth week was positively correlated with the VAS score at 12th week (p=0.039) indicating that pain decreased as the plantar fascia thickness increased. At the fourth week, the plantar fascia was thicker in the ESWT group compared to the CSI group (p=0.048). However, the thickness decreased in both groups at the 12th week. The author noted limitations of the study included: plantar fascia thickness was not measured on the normal foot, patients lost to follow-up, small patient population, and short term follow-up. The authors summarized that extracorporeal shockwave therapy (ESWT) was more efficient in reducing chronic fasciitis pain after 12 weeks than corticosteroid injection. Furthermore, the increase in plantar fascia thickness after ESWT, the more efficient the clinical outcome. However, further long term studies with large patient populations are needed to validate the findings of this study.

Dedes et al. (2018) conducted a nonrandomized controlled trial to evaluate the effectiveness and safety of shockwave therapy in treating tendinopathies. Patients were excluded if they were under the age of 18. The sample consisted of 384 patients suffering from elbow tendinopathy, plantar fasciitis, Achilles tendinopathy or rotator cuff tendinopathy. Three hundred and twenty-six patients received shockwave therapy and 58 patients received conservative treatment making up the control group. The purpose of the study was to investigate the pain reduction, the improvement in the patient’s functionality and quality of life both immediately and four weeks after therapeutic intervention using anonymous questionnaires. Additionally, comparisons were performed between the shockwave intervention group and control group. The shockwave therapy group in patients suffering from plantar fasciitis, elbow tendinopathy, Achilles tendinopathy and rotator cuff tendinopathy reported significant improvements in all parameters measured post-treatment and at the four-week follow-up (p<0.001). The control group also reported significant improvement post-treatment for each type of tendinopathy (p<0.001). However, in the four week follow-up, the results in the shockwave group were significantly better compared to control group. Significant pain reduction and improvement in functionality and quality of life were observed in the both groups of each tendinopathy, but these findings were less pronounced in the control group than those in the shock wave group. Author acknowledged limitation was that direct comparison to other studies was difficult due to the lack of consistent shockwave therapy guidelines. Further research and clinical trials are necessary to clarify the ideal parameters on the efficacy of shockwave therapy.

Sun et al. (2017) performed a meta-analysis of RCTs (n=9 studies/935 subjects) to compare the effectiveness of general ESWT, focused shock wave (FSW), and radial shock wave (RSW) to placebo for chronic plantar fasciitis. RCTs were included that investigated ESWT without anesthesia with sham therapy as control. Therapeutic success in studies was defined as a decrease in visual analogue scale (VAS) score from baseline larger than 50% or 60%, or VAS score of less than 4cm after intervention. Overall, ESWT was found to have higher improvement or success rates than placebo (p<0.00001). A subgroup analysis of FSW and RSW therapies indicated that FSW therapy had greater improvement or success rates than placebo (p<0.0001). Data regarding reduction in pain scale was reported in 4/9 trials. Of these trials, three compared FSW therapy to placebo, and one assessed RSW therapy compared to placebo. Significant heterogeneity was observed in the comparisons of reduction in pain scale. ESWT was found to have greater reduction in pain scale than placebo (p=0.05). No serious adverse events were reported. Limitations of the analysis include the lack of comparison to established treatment methods. The authors concluded that FSW may be associated with higher success rate and greater pain reduction compared to sham therapy in chronic plantar fasciitis patients. However, additional
high-quality clinical trials and systemic reviews are needed to demonstrate the efficacy of ESWT (e.g., FSW, RSW therapies) and determine whether RSW therapy is an ideal alternative therapeutic method to conservative treatment and surgery (Sun, et al., 2017).

A Directory Report published by Hayes reviewed the available literature on focused ESWT for Chronic Plantar Fasciitis. The review included randomized controlled trials (RCTs) (n=17 studies), with studies comparing ESWT to sham treatment (10 RCTs), or to other active treatments (six RCTs), and one RCT comparing full-dose ESWT to low-dose ESWT. Sample sizes ranged from 54–293 patients. Outcome measures in studies were patient-rated pain on visual analog scale (VAS), pain threshold, functional measures, quality of life (QOL), overall treatment success, and complications. Follow-up occurred through five years. Some evidence was found suggesting that ESWT may decrease patient-reported pain and increase functional outcomes in the short term for patients with plantar fasciitis, however study results were conflicting. Most of the complications reported were transient and consisted of swelling, bruising, and pain or discomfort associated with treatment. The overall body of evidence evaluating ESWT for plantar fasciitis was described as large in size and moderate in quality. The authors noted that despite some positive findings, placebo-controlled trials did not consistently demonstrate statistically significant differences in outcomes between ESWT and sham treatment. It was concluded that additional controlled, blinded long-term safety data from well-designed trials on ESWT for plantar fasciitis are needed further evaluate the technology (Hayes, 2016a, reviewed 2018).

Another published Hayes Directory Report reviewed the available literature on radial ESWT for chronic plantar fasciitis. The review included RCTs (n=10 studies), with studies comparing radial ESWT to sham treatment (four RCTs), or to other active treatments (five RCTs), and one RCT comparing radial ESWT with focused ESWT. Sample sizes ranged from 25 to 252 patients. Outcome measures in studies were patient-rated pain on VAS, pain threshold, functional measures, QOL, overall treatment success, and complications. Follow-up ranged from two months to 24 months. Although some of the moderate-size body of evidence suggested that radial ESWT may decrease patient-reported pain and increase functional outcomes in the short term for patients with plantar fasciitis, results were conflicting. When reported, complications were primarily transient and consisted of swelling, bruising, and pain or discomfort associated with treatment. The overall quality of the evidence was low with a small amount of long-term safety data available. Limitations of the of evidence includes methodological weaknesses of individual studies such as lack of long-term follow-up, confounding due to secondary treatments, and high loss to follow-up. Similar to the findings with focused ESWT for the treatment of plantar fasciitis, it was concluded that additional controlled, blinded long-term studies are needed to assess the safety and effectiveness of radial ESWT. Studies identified in a 2018 update of the Hayes Medical Technology Directory report did not change this conclusion. (Hayes, 2016b, reviewed 2018).

A 2016 report issued by the Canadian Agency for Drugs and Technologies in Health (CADTH) reviewed evidence (n=7 systematic reviews) on the effectiveness of shockwave therapy for pain associated with lower extremity orthopedic disorders. Studies included adults with chronic pain associated with lower extremity orthopedic disorders treated (e.g., plantar fasciitis or heel pain; patellar tendinopathy or knee pain; medial tibial stress syndrome, or shin pain) with shockwave therapy or a comparator. Outcomes in studies were pain reduction, reduced need for opioids, and adverse events. Articles comparing different types of SWT without a non-SWT arm were excluded, as well as studies on fracture, cancer pain, arthritis pain, and back pain. The report concluded that there is some suggestion that SWT is an effective treatment option in comparison to placebo for plantar fasciitis. Limited evidence was found to suggest that the effectiveness of SWT is comparable to platelet rich plasma injection, corticosteroid injection or surgery. Adverse effects reported with SWT included skin reddening, bruising at the site of application, and local swelling and pain. Studies demonstrated inconsistent results for SWT used to treat greater trochanteric pain syndrome, patellar tendinopathy, and medial tibial stress syndrome. It was concluded that more evidence is needed to determine whether SWT is more clinically effective than surgery for pain associated with lower extremity orthopedic disorders (CADTH, 2016).

A number of systematic reviews and meta-analysis (n=6–11 studies/550–1287 patients) have evaluated the effectiveness of ESWT in treating chronic plantar fasciitis. These studies have been limited by short-term follow-up of 3–12 months, and have yielded conflicting results. Yin et al. (2014) reviewed low intensity and high intensity ESWT. The authors noted that the pooled data for pain relief in the low-intensity group showed a significant difference between the ESWT and control groups (p<0.001) in favor of ESWT. The high-intensity group was found to have superior pain relief relative to the control group in one trial only. However, with analysis
of short-term function, only low-intensity ESWT was significantly superior over the control treatment. Study results in this review indicated that low-intensity ESWT for the treatment of refractory plantar fasciitis may be more effective than sham treatment. Study limitations of heterogeneity and short-term follow-up made it difficult to draw conclusions regarding efficacy. Dizon et al. (2013) review concluded that when ESWT was compared to placebo, ESWT was more effective in reducing morning pain (p=0.004), but no differences were seen in decreasing overall pain or activity pain (p=0.06 and p=0.07 respectively). In a subgroup analysis, moderate-intensity ESWT was more effective in decreasing overall pain and activity pain (p<0.00001 and p=0.001 respectively). Both moderate- and high-intensity ESWT were more effective in improving functional outcome (p=0.0001). Acknowledged study limitations included the lack of consistency in outcome measures, specified dose intensities (low, medium, high ESWT) and short-term follow-up. Aqil et al. (2013) reported at the 12-week follow-up, patients who received ESWT had better composite pain scores (p=0.02), and greater reduction in their VAS pain scores (p<0.001) compared to placebo. However, there was no significant difference in overall success rate of heel pain improvement between ESWT and placebo (p=0.10). This study also noted limitations which included short-term follow-up and inconsistency of dose intensity. Thomson et al. (2005) reported that a sensitivity analysis including only the four trials of highest quality did not produce evidence of a statistically significant benefit. It was summarized that that this systematic review did not support the use of ESWT for the treatment of plantar heel pain in clinical practice.

An RCT (n=102) by Rompe et al. (2010) reported significantly greater changes in the Foot Function Index sum score for patients managed with plantar fascia-specific stretching (n=54) than for those managed with shock-wave therapy (n=48) (p<0.001) two months after baseline.

A technology assessment of RCTs evaluating the safety and efficacy of ESWT for the treatment of chronic plantar fasciitis was performed for the Canadian Agency for Drugs and Technologies in Health (CADTH). Ho (2007) concluded “the lack of convergent findings from these randomized trials of ESWT for plantar fasciitis suggests uncertainty about its effectiveness. The evidence reviewed does not support the use of this technology for this condition”.

A Cochrane review by Crawford and Thomson (2003) found some indirect evidence that patients’ heel pain improves spontaneously. Patients with heel pain in all trial arms improved spontaneously, regardless of their treatment allocation, demonstrating that the condition is self-limiting in some patients. ESWT was evaluated in five RCTs using different doses, with no consensus reached regarding variation of range of energy (i.e., high versus low), number of pulses, or number of treatment sessions. The results of the meta-analysis found the effectiveness of ESWT for plantar fasciitis unclear.

Numerous studies have investigated the efficacy of ESWT for plantar fasciitis. However, in general, these studies have limitations such as small sample sizes, short-term follow-up, along with variability in results that limit the generalizability of their results. As such, ESWT for this indication remains unproven.

**Insoles with Magnetic Foil:** The theory behind magnet therapy is that magnetic fields create an electrical current that interrupts the transmission of pain signals in the central nervous system as well as increasing blood flow to an area, boosting the flow of oxygen and other nutrients, ultimately reducing pain and swelling. Two RCTs comparing magnetic versus sham insoles for reducing pain have demonstrated that there is no difference between the therapies in patients with plantar fasciitis (Winemiller, et al., 2003; Caselli, et al., 1997). The limited evidence found in the published peer-reviewed literature does not support the use of magnetic insoles for the treatment of plantar fasciitis.

**Intracorporeal Pneumatic Shock Therapy:** Intracorporeal pneumatic shock therapy (IPST) using a pneumatic lithotripter has also been proposed for the treatment of chronic plantar fasciitis. Lithotripsy with this device is commonly used to treat kidney and bladder stones.

Few studies exist in the published peer-reviewed medical literature evaluating the safety and effectiveness of IPST for the indication of plantar fasciitis. Dogramaci et al. (2010) conducted an RCT (n=50) in which patients were assigned to treatment with IPST (n=25) or to a placebo group (n=25). At six months of follow-up the rate of successful outcomes (i.e., pain, function) in the treatment group were significantly higher compared to the control.
group (p<0.001). No complications caused by the procedure were observed during the study. Study limitations include small sample size and short-term follow-up.

There is insufficient evidence in the published peer-reviewed medical literature to support IPST for the treatment of plantar fasciitis.

**Laser Therapy:** Laser therapy, also called low-level laser therapy (LTLT) is a form of phototherapy which involves the application of low-power monochromatic and coherent light to injuries and lesions to stimulate healing. LTLT is used to increase the speed, quality and tensile strength of tissue repair, resolve inflammation, and give pain relief.

Cinar et al. (2018) performed a randomized controlled trial (RCT) comparing the efficacy of low-level laser therapy (LTLT) and exercise to orthotic support and exercise (usual care) in the treatment of plantar fasciitis. The patients were randomized into two groups: LTLT (n=27) and control (n=22). The LTLT group received a home exercise program with orthotic support and a gallium-aluminum-arsenide laser with a 850-nm wavelength for ten sessions, three times a week. The control group received home exercise program with orthotic support. Patients were included per the following criteria: pain located on the medial tubercle or along the medial process of the plantar fascia persisting for at least one month with a minimum score of five on the 10-point visual analog scale (VAS), pain felt over the plantar fascia in the morning at first step in the week prior to enrollment, tenderness to palpation over the medial calcaneal tuberosity or along the plantar fascia, age 18 and older, and agreement to complete treatment and follow-up assessments. Functional outcomes were measured by function subscale of American Orthopedic Foot and Ankle Society Score (AOFAS-F) and 12-min walking test including walking speed, cadence, and activity-related pain using visual analog scale (VAS). The scores were recorded at baseline, third week, and third month after the treatment with three patients being lost to follow-up. There was a significant improvement in AOFAS-F total score at three weeks in both groups (LTLT, p<0.001; control, p=0.002). The groups were comparable with each other for both walking speed and cadence at all assessment times (p>0.05). Both groups showed significant reduction in pain over three months (LTLT, p<0.001; control, p=0.01); however, the LTLT group had lower pain than the control group at three months (p=0.03). Study limitations included: the lack of standardization of the LTLT dose and frequency along with the position of the foot during treatment and the lack of a non-treatment group. The authors concluded that combination therapy of LTLT with usual care is more effective to improve functional outcomes and activity-related pain when compared to usual care alone. Additional randomized controlled trials with larger patient populations and long-term follow-up are needed to support the outcomes of this study.

Ulusoy et al. (2017) reported the results of an RCT (n=60) comparing the effectiveness of low-level laser therapy (LTLT), therapeutic ultrasound (US) therapy, and extracorporeal shock wave therapy (ESWT) using magnetic resonance imaging (MRI). Inclusion criteria were symptoms of a chronic calcific or plantar heel pain for six months unresponsive to six weeks of conservative treatment (e.g., nonsteroidal anti-inflammatory drug, home exercise program, and standard insoles). Exclusion criteria included previous local trauma, foot surgery, local steroid injection within the previous three months, diabetes mellitus, and plantar fascial rupture. Patients were randomized into three treatment groups: Group one underwent 15 sessions of LTLT; group two underwent 15 sessions of continuous US; and group three underwent three sessions of ESWT. The primary outcome was defined as a 60% decrease in heel pain for two VAS measurements. Secondary outcome measures were a functional response to treatment and a reduction in plantar fascial thickness on MRI. Data from 54 patients were analyzed for the primary outcome and 52 for the MRI evaluations. At six-week follow up, the VAS score had significantly decreased and the AOFAS scale scores had significantly improved after treatment in all three groups (p<0.05). In the comparison, LTLT and ESWT were found to be more effective than US therapy, with no significant difference found between LTLT and ESWT in the success rate (VAS score 60%). A significant decrease was found in fascia thickness in all three groups after treatment. No statistically significant difference was found between the groups in the reduction of the fascia thickness measured on MRI. Side effects were not observed in any patient. Study limitations include small patient population and short follow-up timeframe. Study results suggest that LTLT and ESWT may be superior to therapeutic US in decreasing pain associated with chronic calcific or plantar fasciitis. However additional well-designed studies with sample sizes are needed to draw conclusions on treatment effectiveness for this indication.
Macias et al. (2015) performed a placebo-controlled, randomized, double-blind, multicenter study to evaluate the clinical utility of low-level laser therapy for the treatment of unilateral chronic fasciitis. Patients were included who had a primary complaint of heel pain on weight-bearing after a period of rest; chronic heel pain that persisted three months with no evidence of acute trauma to the heel; average self-rating pain score of 50 using a 100-point visual analog scale (VAS) after taking some initial steps following a period of rest both on the day of study qualification and at baseline; and heel pain that was unresponsive to any conservative form of plantar fasciitis care (i.e., rest, taping, stretching, orthotics, shoe modifications, night splinting, casting, physical therapy, prescription NSAIDs when taken for a minimum period of two weeks, or local corticosteroid injections). Exclusion criteria included mechanical posterior heel pain categorized as insertional Achilles tendonitis or bursitis; neurologic or arthritic heel pain; type 1 diabetes; sensory neuropathy; or peripheral vascular disease. Participants were treated twice a week for three weeks and were evaluated throughout eight weeks. Pain ratings were recorded using a VAS. At the final follow-up, the treatment group demonstrated a statistically significant improvement (p<0.001) in heel pain compared to the placebo subjects. No adverse events were reported. Study results are limited by small sample size and short-term follow-up period.

In a randomized, double-blind, placebo-controlled trial (n=25), Kiritsi et al. (2009) compared the effect of low-level laser therapy (LLLT) (n=15) versus placebo (n=10) on plantar fasciitis. Outcomes were documented by ultrasound of the plantar fascia and reported pain scores. Enrolled patients had unilateral plantar fasciitis, so the contralateral asymptomatic fascia was used as control. Pain levels were reported to be significantly improved after LLLT compared to the placebo group (i.e., after night rest [p=0.006], with daily activities [p=0.01]). The small sample size of this study limits the generalizability of results.

Basford et al. (1998) conducted a randomized, double-blinded, placebo-controlled clinical study of 32 subjects comparing dummy versus active laser therapy over four weeks using relief of pain as the endpoint. No significant differences were found between the groups in pain scores either during treatment or at one-month follow-up.

The available data regarding the efficacy of laser therapy for the treatment of plantar fasciitis is limited.

**Low-Load Prolonged-Duration Stretch (LLPS) Devices:** LLPS also referred to as dynamic splinting uses a prolonged duration stretch with calibrated, adjustable tension to increase time at end range of motion and thereby reducing contracture. Stretching with dynamic splinting has been proposed as a treatment for plantar fasciitis because the tension can adapt to changes in the plantar fascia. Available LLPS/dynamic splinting devices include:

- Dynasplint System® (Dynasplint Systems, Inc., Severna Park, MD)
- Ultraflex (Ultraflex Systems, Pottstown, PA)
- Pro-glide™ Dynamic ROM devices (DeRoyal®, Powell, TN)
- Advance Dynamic ROM® devices (Empi, St. Paul, MN)

Studies in the published peer-reviewed medical literature evaluating the safety and effectiveness of include an RCT (n=60) by Sheridan et al. (2010). All patients received nonsteroidal anti-inflammatory drugs, orthoses, and corticosteroid injections as needed. The experimental group (n=30) also received dynamic splinting worn at night to obtain a LLPS with dynamic tension. A significant difference was found in the mean change from baseline in Plantar Fasciopathy Pain/Disability Scale scores of experimental over control patients (p<0.0001).

Although the results of one RCT suggest that dynamic splinting may be effective in reducing the pain of plantar fasciopathy, additional well-designed randomized controlled clinical trials with adequate patient populations and follow-up are needed to support the safety and efficacy of this intervention. There is insufficient evidence in the published peer-reviewed literature to support the use of LLPS /dynamic splinting for plantar fasciitis.

For additional information, refer to the Cigna Stretch Devices for Joint Stiffness and Contractures Coverage Policy.

**Microwave Diathermy:** Microwave diathermy uses microwave radiation to create heat within the tissues. There is no evidence supporting the efficacy of this modality in the treatment of plantar fasciitis (Crawford and Thomson, 2003).
**Percutaneous Ultrasonic Ablation:** Percutaneous ultrasonic ablation is also being investigated as a treatment for refractory plantar fasciitis. Ultrasonic ablation devices break up degenerative soft tissue via ultrasound guidance so that the damaged tissue can be aspirated or removed. According to the manufacturer, “the Tenex Health TX® combines conventional ultrasound imaging for visualization with the advanced TX MicroTip® for rapid and precise cutting and removing of diseased soft tissue in the plantar fascia” (Tenex, 2017). The Tenex Health TX System® (Tenex Health, Inc., Lake Forest, CA) was granted marketing approval by the FDA via the 510(k) process on March 3, 2016, because it is considered to be substantially equivalent to another device already on the market. The 510(k) summary stated that the system is substantially equivalent to the TX1 Tissue Removal System. Under the FDA 510(k) approval process, the manufacturer is not required to supply to the FDA evidence of the effectiveness prior to marketing the device. The system consists of a console that houses user functions (e.g., irrigation and aspiration pumps), ultrasonic hand piece, inflation cuff, and foot pedal which controls the device functions. The FDA states that the Tenex Health TX System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue are desirable, including general surgery, orthopedic surgery, laparoscopic surgery and plastic and reconstructive surgery (FDA, 2016).

There is a paucity of studies investigating the safety and efficacy of ultrasonic ablation for plantar fasciitis consisting of few case series with small patient populations (Sanchez, et al., 2017; Patel, 2015). A Hayes Search and Summary report reviewed abstracts and in general found insufficient published evidence to assess the safety and/or impact on health outcomes or patient management of the Tenex Health TX Procedure for treatment of tendon pain” (Hayes, 2015; 2017). Based on the lack of published data, the procedure is considered unproven for the treatment of chronic plantar fasciitis.

**Pulsed Radiofrequency Electromagnetic Field (PREF) Therapy:** Pulsed radiofrequency electromagnetic field (PREF) is noninvasive modality that delivers electromagnetic energy into soft tissue, generating an electric field that is thought to facilitate a therapeutic effect. The exact mechanism by which PREF interacts with cells to initiate a therapeutic effect is not fully understood (Rawe, 2012). PREF has been investigated for indications such as postoperative pain control, wound healing, soft tissue injury and more recently for treatment of plantar fasciitis therapy.

There is paucity of evidence in the published peer-reviewed medical literature evaluating the safety and effectiveness of PREF for plantar fasciitis. A double-blind, multicenter, randomized, placebo-controlled study (n=70) was used to evaluate a small, wearable, extended-use PREF device worn overnight. The primary outcome measure was morning pain. A significantly different decline was reported between the study and control groups (p=0.03). Although the results of this small study are positive, there is currently insufficient evidence demonstrating safety and efficacy of PREF for the indication of plantar fasciitis (Brook, et al., 2012).

**Radiotherapy:** Radiotherapy for plantar fasciitis treatment has been well-established in Germany for many years. The exact radiobiological mechanisms of the effect of ionizing radiation on plantar fasciitis have not been completely investigated and understood.

Canyilmaz et al. (2015) conducted an RCT (n=128 patients) comparing radiation therapy (n=64) to local steroid injections (n=64) for plantar fasciitis. Patients age 40 or older were included if they had symptoms longer than six months and a clinical diagnosis of a painful heel spur. Patients who had previous radiation therapy, trauma to the foot, severe psychiatric disorders, rheumatic and/or vascular diseases, or were pregnant or breastfeeding were excluded from the study. The primary endpoint was pain reduction measured by several pain scales including the visual analog scale (VAS). The median follow-up period for all patients was 12.5 months (range, 6.5-18.6 months). At six-month follow-up, the mean differences in VAS scores after treatment compared with the values before radiation therapy was 2.7 in the radiation therapy arm and 4.6 in the steroid injection group. There was a statistically significant difference in favor of radiation therapy (p<0.001). Results in the short-term indicate that radiation therapy has a greater analgesic effect on pain from plantar fasciitis than steroid injections. However long-term study results are needed to support this finding.

An RCT (n=66) by Niewald et al. (2012) assigned patients with painful heel spur/plantar fasciitis to receive a standard dose versus a low dose of radiation therapy. Follow-up continued through one year. After three months the results in the standard arm measured by visual analogue scale were significantly improved compared to
those in the low-dose arm (p=0.001). At 12 months follow-up significant fewer patients were re-irradiated in the standard arm compared with the low-dose arm (p<0.001). Patients who had a favorable result after three months showed this even after 12 months.

Miszczyk et al. (2007) evaluated the effectiveness of radiotherapy and assessed the impact of fraction dose (fd) compared to total dose (TD) in the treatment of 856 patients with plantar fasciitis. Outcome measures included pain relief level, period of anesthetic effect preservation after treatment, presence of pain and the timing of its appearance, and analgesia use. Complete follow-up data were available for 327 patients. The mean follow-up period was 74 months. After treatment, a lack of pain was reported by 48% of the patients. Pain relief greater than 50% was reported by 21% of patients and 17% reported pain relief less than 50%. The mean pain relief duration was 72 months. The last follow-up, 25% of these patients reported having pain at rest and 32% had pain while walking. A dose-effect relationship was not found. This study is limited by its retrospective, nonrandomized design and loss to follow-up.

Further research is needed to demonstrate the safety and efficacy of radiotherapy for the treatment of plantar fasciitis.

Stereotactic Radiofrequency Thermal Lesioning: Stereotactic radiofrequency thermal lesioning, or radiofrequency lesioning, is a minimally invasive procedure, in which a probe the size of a needle is placed through the skin in the heel in the area of pain. While the patient is under intravenous (IV) sedation, the tip of the probe heats up to 87° Celsius (189° Fahrenheit), and is kept there for 90 seconds. The proposed mechanism of action is desensitization of the nerve endings. In a retrospective study of 39 patients, Sollitto et al. (1997) found that 92% of patients experience resolution of symptoms. This study is limited by the lack of a control group and randomization; a more rigorous design is needed.

Trigger-Point Needling and Infiltration: Trigger-point needling for plantar fasciitis is the needling and infiltration of anesthetic into the myofascial trigger points at the proximal portion of the medial gastrocnemius muscle. Rastegar et al. (2018) performed a single blind randomized controlled trial (RCT) comparing the efficacy of dry-needling to steroid injection in the treatment of plantar fasciitis. The patients were randomized into two groups: steroid group (n=34) and dry needling group (n=32). The steroid group received an injection containing 1 ml (40 mg/ml) of methylprednisolone acetate into the intended site. The dry-needling group received dry needling using a 0.30-mm needle that was gradually withdrawn and advanced for 30 seconds in the same location as the steroid group. Eligible patients were individuals over age 18 with a three month history of plantar heel pain and diagnosed with plantar fasciitis. The primary outcome measured was plantar pain intensity on the visual analogue scale (VAS) before treatment and at each follow-up. Patients were assessed before treatment, at three weeks, six weeks, three months, six months and one year following treatment. At the three week follow-up, the VAS score was clinically significant in favor of the steroid group (p<0.001). At the six month and one year follow-up, the VAS scores were clinically significant in favor of the dry-needling group (p<0.001, p=0.004), respectively. There were no significant differences between groups at the other time points. The results suggested that steroid injections quickly reduced pain, but after six weeks of treatment the pain increased. In the dry-needling group, pain reduced slowly, but after six weeks of treatment, pain continued to decline. At the end of the study, average pain in the steroid group was greater than in the dry-needling group. The author noted limitations of the study included: the medial plantar region injection point was used as the location for steroid injection and dry needling (where most pain had been focused on) and the needles were not guided using imaging techniques. Additional randomized controlled trials with larger patient populations and long-term follow-up are needed.

He et al. (2017) performed a meta-analysis (n=7 RCTs/417 patients) to evaluate the effect of dry needling of myofascial trigger points (MTrPs) in patients with plantar heel pain. The number of participants in studies ranged from 20–108. Subjects were adults diagnosed with planter heel pain (plantar fasciitis), with interventions of dry needling/acupuncture of the MTrPs compared to placebo or other treatment as control. Outcome measures included visual analog scale (VAS) score, success rate for pain, and adverse events. Success for pain was defined as a minimum decrease of 50% in VAS scores. Follow up occurred through 12 months. Pooled results showed that MTrP needling significantly reduced the VAS score (p<0.001) compared to control. No significant differences were found between the two interventions in terms of success rate for pain and the incidence of adverse events which were transient. Acknowledged limitations of the analysis include the small sample sizes...
and substantial heterogeneity of studies. Larger well-designed RCTs are needed to support safety and efficacy of MTrP needling for plantar fasciitis.

Cotchett et al. (2014) published their results of a parallel-group, participant-blinded RCT (n=84 patients) of patients with plantar heel pain for at least one month. The mean duration of plantar heel pain was 13.6 months. Subjects were assigned to receive real or sham trigger point dry needling. The treatment consisted of one treatment per week for six weeks. The follow-up period was 12 weeks. Primary outcomes included first-step pain measured with a visual analog scale (VAS), and general foot pain. The secondary outcome measures included foot function and general foot health. The primary end point for predicting the effectiveness of dry needling for plantar heel pain was six weeks. A total of 81 subjects (96.4%) completed the six-week follow-up, and 79 subjects (94.0%) completed follow-up at 12 weeks. At six weeks of follow-up, both groups showed decreased pain but there were significant between-group effects that favored real dry needling over sham dry needling. At six and 12 weeks, there were no significant differences in health-related quality of life between groups. The most common delayed adverse event was bruising, followed by an exacerbation of symptoms. These results suggest that dry needling is more effective than sham for first-step plantar heel pain. However the study results are limited by the single-blind design, relatively small sample size, and short-term follow-up which preclude generalizability.

Cotchett et al. (2010) conducted a systematic review to evaluate the evidence for the effectiveness of dry needling and/or injections alone or in combination with acupuncture. Outcome measures of pain and function were assessed. A total of three quasi-experimental trials (n=53 patients) matched the inclusion criteria: two trials found a reduction in pain for the use of trigger point dry needling when combined with acupuncture and the third found a reduction in pain using 1% lidocaine injections when combined with physical therapy. The methodological quality of the three trials was found to be poor. A meta-analysis was not conducted because substantial heterogeneity was present between trials.

Imamura et al. (2003) conducted a randomized, controlled study of 64 subjects comparing conventional physical therapy to physical therapy plus injection of 1% lidocaine to the taut band at the proximal portion of the medial gastrocnemius muscle of the involved limb. Statistically significant reduction of pain and improvement in function were found in both groups without difference between them. However, the time required to achieve the same improvement was significantly less in the injected group than in the control group. Post-injection soreness and local hematoma were found in 30% of the patients receiving trigger-point needling. Additional studies are needed to support the effectiveness of this therapy.

**Professional Societies/Organizations**

**American College of Foot and Ankle Surgeons (ACFAS):** According to a consensus statement on the diagnosis and treatment of adult acquired infracalcaneal heel pain, extracorporeal shockwave therapy (ESWT) is safe and effective in the treatment of plantar fasciitis. The ACFAS stated that “since ESWT has few negative consequences and the recovery time is short, with patients typically walking and returning to full activities within a few days, the panel thought that ESWT is a valuable option for providers treating heel pain”. This recommendation was made using systematic reviews with meta-analysis of randomized controlled trials. Additional randomized controlled trials with larger patient populations and long-term follow-up are needed to support the outcomes of the mentioned studies (Schneider, et al., 2018).

The panel also determined that injection techniques (e.g., amniotic tissue, platelet-rich plasma, botulinum toxin, needling, and prolotherapy) or other surgical techniques (e.g., ultrasonic debridement using a microtip device, cryosurgery, and bipolar radiofrequency ablation) were uncertain, neither appropriate nor inappropriate (Schneider, et al., 2018).

**Use Outside of the US**
The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating therapeutic goods including medicines, medical devices, blood and blood products. Any product for which therapeutic claims are made must be listed, registered or included in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia. The following devices are included in the ARTG listing:
1. Orthopaedic extracorporeal shock wave therapy system (Dornier MedTech GmbH, Wessling, Germany) as of September 9, 2010; intended use is for treating musculoskeletal disorders (e.g., tendinopathies and soft tissue pain near bones, plantar fasciitis, epicondylopathy) and other related muscle pain syndromes.

2. Electromechanical orthopaedic extracorporeal shock wave therapy system (Richard Wolf GmbH, Knittlingen, Germany) as of February 11, 2012; intended use is for the elimination of chronic pain using focused, extracorporeal shock wave therapy and trigger point shock wave therapy.

In January 2013, the National Institute for Health and Clinical Excellence (NICE) issued an interventional procedure guidance stating that the evidence on autologous blood injection for plantar fasciitis raises no major safety concerns. However 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, 2103).

According to a NICE guidance on the use of ESWT for refractory plantar fasciitis a review of the evidence raises no major safety concerns; however, current evidence on the efficacy of ESWT for this indication is inconsistent. Therefore, the procedure should only be used with special arrangements for clinical governance, consent and audit or research (NICE, 2009).

### Coding/Billing Information

**Note:**

1. This list of codes may not be all-inclusive.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Experimental/Investigational/Unproven when used to report any of the above therapies for the treatment of plantar fasciitis:**

<table>
<thead>
<tr>
<th>CPT® Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>20552</td>
<td>Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)</td>
</tr>
<tr>
<td>20553</td>
<td>Injection(s); single or multiple trigger point(s), 3 or more muscle(s)</td>
</tr>
<tr>
<td>20999</td>
<td>Unlisted procedure, musculoskeletal system, general</td>
</tr>
<tr>
<td>28890</td>
<td>Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia</td>
</tr>
<tr>
<td>28899</td>
<td>Unlisted procedure, foot or toes</td>
</tr>
<tr>
<td>77401</td>
<td>Radiation treatment delivery, superficial and/or ortho voltage, per day</td>
</tr>
<tr>
<td>97024</td>
<td>Application of a modality to 1 or more areas; diathermy (eg, microwave)</td>
</tr>
<tr>
<td>97139</td>
<td>Unlisted therapeutic procedure (specify)</td>
</tr>
<tr>
<td>97799</td>
<td>Unlisted physical medicine/rehabilitation service or procedure</td>
</tr>
<tr>
<td>0101T</td>
<td>Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy</td>
</tr>
<tr>
<td>0232T</td>
<td>Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1815</td>
<td>Dynamic adjustable ankle extension/flexion device, includes soft interface material</td>
</tr>
<tr>
<td>E1816</td>
<td>Static progressive stretch ankle device, flexion and/or extension, with or without range of motion adjustment, includes all components and accessories</td>
</tr>
<tr>
<td>P9020</td>
<td>Platelet rich plasma, each unit</td>
</tr>
<tr>
<td>S8948</td>
<td>Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser, each 15 minutes</td>
</tr>
</tbody>
</table>
References


47. Ibrahim MI, Donatelli RA, Schmitz C, Hellman MA, Buxbaum F. Chronic plantar fasciitis treated with two sessions of radial extracorporeal shock wave therapy. Foot Ankle Int. 2010 May;31(5):391-7.


