Cigna Medical Coverage Policy

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Subject **Plantar Fasciitis Treatments**

Table of Contents

Coverage Policy 1
General Background 2
Coding/Billing Information 11
References 12

Hyperlink to Related Coverage Policies

Acupuncture
Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions
Lower Limb Orthoses and Shoes
Low-Level Laser Therapy
Physical Therapy
Stretch Devices for Joint Stiffness and Contractures
Tissue-Engineered Skin Substitutes and Platelet-Derived Growth Factors

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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.

Cigna covers open or endoscopic plantar fasciotomy as medically necessary for the treatment of plantar fasciitis following the failure of six months of appropriate medical therapy.

Cigna does not cover ANY of the following for the treatment of plantar fasciitis because these interventions are considered experimental, investigational or unproven (this list may not be all-inclusive):

- acupuncture
- autologous platelet-derived growth factors
- coblation® (e.g., Topaz™)
- cryosurgery
- 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/dynamic splinting (e.g., Dynasplint System®, Ultraflex, Pro-glide™ Dynamic ROM, Advance Dynamic ROM®)
- microwave diathermy
- pulsed radiofrequency electromagnetic field (PREF) therapy
- radiotherapy
- stereotactic radiofrequency thermal lesioning
- trigger-point needling and infiltration of the proximal medial gastrocnemius muscle

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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 tubercule 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 (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.

Acupuncture: Acupuncture is a method of producing analgesia or treating disease by stimulating anatomical locations on the skin by the penetration of needles. There are no studies specific to its efficacy in the treatment of plantar fasciitis. The overall body of evidence in general is of poor quality, consisting of numerous uncontrolled studies, case series and case reports. There is no evidence that supports the efficacy of acupuncture for the treatment of plantar fasciitis.

Autologous Platelet-Derived Growth Factors: Autologous platelet-derived growth factors (APDGF) also referred to as autologous platelet concentrate , platelet-rich plasma, 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.

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 (de Vos, et al., 2010).

Lee and Ahmad (2007) conducted a prospective, randomized, controlled, observer-blinded study (n=64) to compare the efficacy of intralesional 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 include 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 recently 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.

A prospective, double-blind RCT (n=80) to evaluate the effectiveness of Coblation-based fasciotomy using the Topaz MicroDebrider is currently underway. The primary outcome measure for this study will be pain relief. Secondary outcomes will include a comparison of postoperative complications and an assessment of function and quality of life by the SF-36 questionnaire. There were no studies identified in the published peer-reviewed literature that assess the effectiveness of Coblation-based fasciotomy for relieving pain associated with plantar fasciitis. Therefore, Coblation technology for this indication is unproven at present.

Cryosurgery: Cryosurgery is a minimally invasive procedure that involves the use of extreme cold to destroy abnormal tissue. There is a paucity of studies investigating the efficacy of cryosurgery for the treatment of recalcitrant plantar fasciitis in the peer-reviewed medical literature. A retrospective case series (n=137) by Cavazos et al. (2009) reported success and failure rates of 77.4% and 22.6%, respectively for chronic plantar fasciitis patients treated with cryosurgery. A mean pain score decreased from 7.6 before cryosurgery to 1.1 ($p < 0.0005$).at 24 months of follow-up. This study is limited by its retrospective, uncontrolled design.

Allen and colleagues (2007) utilized cryosurgery for 59 consecutive patients (61 heels) who had failed prior conservative therapy and were considered surgical candidates. Study results suggested that pain decreased significantly after the procedure ($p<.0001$). However, the nonrandomized design and small sample size of this study decrease its generalizability.

Based on the lack of published data, cryosurgery is considered unproven for the treatment of plantar fasciitis.

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).

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).

Comparative studies have also not consistently demonstrated a greater reduction in heel pain for ESWT versus standard treatment options. A prospective series (n=37) by Othman and Ragab (2010) compared results of patients with chronic plantar fasciitis who were treated with endoscopic plantar fasciotomy to those treated with ESWT. The mean follow-up was 11 months for the fasciotomy group (n=17) and 7.6 months for the ESWT group (n=20). Endoscopic plantar fasciotomy was reported to give better results than ESWT, but with minor complications. It was noted that additional studies with larger populations and longer term follow-up is needed to determine the curative effects of ESWT (Othman and Ragab, 2010).

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.

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 Shockwave treatment was found to be no more effective than conventional physiotherapy three months after the end of treatment. An RCT (n=149) by Wang et al. (2006) 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.

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

Tice (2007) performed a technology assessment of ESWT for musculoskeletal disorders prepared for the California Technology Assessment Forum (CTAF). The report evaluated RCTs (n=14 studies) and found three of the clinical trials (n=610 subjects) to be of good quality, with the remaining eleven studies having methodological flaws due to inadequate blinding, different co-interventions, and/or loss to follow-up. Outcomes assessed included self-assessment of pain, typically measured with a visual analog scale (VAS). ESWT for plantar fasciitis did not meet CTAF’s assessment criteria for safety, effectiveness, and improvement in health outcomes. The report summarized that there was a tremendous amount of variability in the quality of the randomized trials and in the interventions studied. The best quality studies found minimal evidence for benefit compared with sham ESWT. The fair to poor quality studies did demonstrate 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 bias the study results in favor of ESWT. There was clear evidence of publication bias. The totality of the evidence suggests little or no benefit to ESWT for plantar fasciitis beyond the placebo effect. Until unequivocal benefit is demonstrated in high quality clinical trials, ESWT should remain investigational.

The ECRI Institute issued an evidence report on the use of ESWT for the treatment of plantar fasciitis in 2006. The evidence included RCTs (n=13) and case series (n=7) with a total of 2,233 patients. Only four trials that used a single high-energy treatment met inclusion criteria for the analysis. Study results indicated that patients treated with a single session of high energy ESWT had less pain on the first few steps in the morning than

patients given a sham treatment. No evidence-based conclusion could be reached by ECRI as to whether patients treated with a course of low or medium energy ESWT had less, more, or the same amount of pain than patients given a sham treatment. It was summarized that ESWT is a safe procedure that may provide some relief from the pain of chronic plantar fasciitis; however, the degree of pain relief may not be clinically significant (ECRI, 2006).

Systematic Reviews/Meta-analyses: Aqil et al. (2013) conducted a meta-analysis of prospective RCTs (n=7 studies/663 subjects) to investigate whether there was a significant difference in the change of pain scores from baseline when treated with ESWT (n=294 subjects) and placebo (n=369 subjects). Inclusion criteria for studies were adult patients who continued to be symptomatic despite a minimum of three months of conservative treatments. At 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. There was no significant difference in overall success rate of heel pain improvement between ESWT and placebo ($p= 0.10$). Limitations of the review include short-term follow-up and inconsistency in the types of shock waves administered in the included trials.

Dizon et al. 2013 conducted a systematic review and meta-analysis of clinical trials (2002-2010) to evaluate the effectiveness of ESWT in treating chronic plantar fasciitis. RCTs (n=11studies1287 patients) were included if they compared ESWT to placebo or standard care. The primary outcome measure of interest was overall pain reduction assessed 12 weeks after intervention. Other primary outcome measures considered were pain during the first few steps in the morning and during activity. Other pain outcomes such nocturnal pain and pain at pressure were not included in the meta-analysis because these are not typical characteristics of pain in plantar fasciitis. Compared to placebo control, ESWT was more effective in reducing morning pain ($p=0.004$). There was no difference between ESWT and control in decreasing overall pain, ($p= 0.06$), however moderate-intensity ESWT was more effective in decreasing overall and activity pain ($p<0.00001$). There was no significant difference in the effectiveness of decreasing activity pain ($p= 0.07$). Both moderate- and high-intensity ESWT were more effective in improving functional outcome ($p= 0.0001$). The adverse effects that were seen more in ESWT were pain on the calcaneal area and calcaneal erythema. Acknowledged study limitations include the lack of consistency in outcome measures, specified dose intensities, and follow-up (Dizon, et al., 2013).

Thomson et al. (2005) performed a systematic review and meta-analysis to investigate the effectiveness of ESWT and to provide a precise estimate of the likely benefits of this therapy. A total of eleven RCTs met inclusion criteria for review. Conclusions were based on a pooled analysis of six RCTs (n=897). The meta-analysis was statistically significant in favor of ESWT for the treatment of plantar heel pain, but the effect size was very small. A sensitivity analysis including only the four trials of highest quality did not produce evidence of a statistically significant benefit. The authors stated that this systematic review does not support the use of ESWT for the treatment of plantar heel pain in clinical practice (Thomson, et al., 2005).

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

Ogden et al. (2002) conducted a meta-analysis of eight prospective RCTs evaluating the effectiveness of ESWT for plantar fasciitis (n=840). Treatment success was variably defined as complete or substantial relief of pre-procedure symptoms, activity limitations, or both. Success rates for five studies using low-energy shock waves ranged from 58–88% (Rompe, et al., 1996; Rompe, et al., 1997; Krischek, et al., 1998; Dahmen, et al., 1995; Buch, et al., 2000). For the three studies that utilized high-energy shock waves, the success rates ranged from 81–87% (Ogden, et al., 2001; Chen, et al., 2001; Wang, et al., 2000).

Extracorporeal Pulse Activation Therapy (EPAT®): More recently a variation of ESWT, referred to as EPAT and also known as extracorporeal acoustic wave therapy), has been proposed for orthopedic conditions and soft tissue inflammation. EPAT is described as low-energy pulse-activated shockwave that may propose tissue healing.

U.S. Food and Drug Administration (FDA): The D-ACTOR Vibration Massager System (Storz Medical AG, Tagerwilen, Switzerland) was granted marketing approval by the FDA via the 510(k) process on June 27, 2008. The D-Actor 200 is described as "a vibrating percussion massage system that operates by compressed air to perform pulse activation therapy on target muscles and tissues." The device is intended to be used for the temporary increase in local blood circulation to relieve minor muscle aches and pains (FDA, 2008).

Literature Review: Very limited data exists in the published peer-reviewed literature that is specific to the safety and effectiveness of EPAT. A case series (n=60) by Saxena et al. (2011) examined the use of EPAT for achilles tendinopathy and reported an overall pain improvement rate of 78% at one year follow-up.

There is insufficient evidence to support the use of EPAT for the treatment of any orthopedic condition. Evidence in the form of randomized controlled studies with long-term follow-up is needed to determine safety and efficacy of this type of shockwave therapy.

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.

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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.

Very 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 (LLLT) is a form of phototherapy which involves the application of low-power monochromatic and coherent light to injuries and lesions to stimulate healing. LLLT is used to increase the speed, quality and tensile strength of tissue repair, resolve inflammation, and give pain relief.

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/Dynamic Splinting: Dynamic splinting uses low-load, prolonged duration stretch (LLPS) 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).

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, treatment of 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.

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.

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 been incompletely investigated and understood.

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.

In 2001, the Patterns of Care Study in Benign Diseases Panel of the German Society for Radiation Oncology distributed a standardized questionnaire to all radiotherapy departments in Germany to determine their experience with radiotherapy for plantar fasciitis (Micke, et al., 2004). The records of 7947 patients were prospectively evaluated over a median follow-up period of 28 months for reduction in pain scores. Several different types of equipment and doses of radiation were utilized among the centers. No dose-response relationship could be established. Complete relief of pain for more than three months was reported in a median of 70% of all treated patients, and pain relief lasting a minimum of 12 months was reported in 65% of patients. No statistical analysis of the significance of these percentages was reported.

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. 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
According to a practice guideline from the American College of Foot and Ankle Surgeons (ACFAS), tier one treatment options for plantar heel pain associated with plantar fasciitis include foot padding and strapping, therapeutic orthotic insoles, cortisone injections, and Achilles and plantar fascia stretching for a period of six weeks. Second tier treatment options include continuation of tier one treatments, with consideration for additional therapies, including the use of night splints to maintain an extended length of the plantar fascia and

gastroc-soleus complex. The guideline states that ESWT may be considered as an alternative to traditional surgical approaches for recalcitrant plantar heel pain (Thomas, et al., 2010).

In a joint policy statement, the American Podiatric Medical Association (APMA) and the American College of Foot and Ankle Surgeons (ACFAS) acknowledge that ESWT is one of the many procedures used to treat plantar fasciitis. Despite the limited evidence from relatively small studies, few randomized trials, and conflicting results identified in the literature, the APMA/ACFAS concluded that "ESWT appears to be an efficacious, FDA-approved, non-surgical option in the treatment of chronic proximal plantar fasciitis" (APMA/ ACFAS, 2003).

Use Outside of the US
The Australia and New Zealand Horizon Scanning Network's (ANZHSN) scanning program is a collaborative Commonwealth and State initiative guided by the Health Policy Advisory Committee on Technology (HealthPACT), which provides jurisdictions with evidence-based advice on emerging technologies. A 2004 ANZHSN Horizon Scanning prioritizing summary on ESWT for chronic rotator cuff calcific tendonitis determined the level of use in Australia to be limited, stating that the technology is available through sports medicine clinics (ANZHSN, 2004).

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, 2009b).

Summary
Conservative first- and second-line treatments for plantar fasciitis are most often successful. For those who fail medical management, plantar fasciotomy or plantar fascia release may be considered. A number of unproven treatment modalities have been proposed for plantar fasciitis, the most controversial of which is extracorporeal shock wave therapy (ESWT). The evidence in the published peer-reviewed literature regarding the efficacy of ESWT, as well as the following proposed treatment options, remains inconclusive at this time:

- acupuncture
- autologous platelet-derived growth factors
- coblation® (e.g., Topaz™)
- cryosurgery
- 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/dynamic splinting (e.g., Dynasplint System®, Ultraflex, Pro-glide™ Dynamic ROM, Advance Dynamic ROM®)
- microwave diathermy
- pulsed radiofrequency electromagnetic field (PREF) therapy
- radiotherapy
- stereotactic radiofrequency thermal lesioning
- trigger-point needling and infiltration of the proximal medial gastrocnemius muscle

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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

Covered when medically necessary:

CPT®* Codes	**Description**
28008	Fasciotomy, foot and/or toe
29893	Endoscopic plantar fasciotomy

Experimental/Investigational/Unproven/Not Covered when used for the treatment of plantar fasciitis:

CPT* Codes	**Description**
20552	Injection(s); single or multiple trigger point(s), one or two muscle(s)
20553	Injection(s); single or multiple trigger point(s), three or more muscle(s)
28890	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia
28899†	Unlisted procedure, foot or toes
64632	Destruction by neurolytic agent; plantar common digital nerve
77401	Radiation treatment delivery, superficial and/or ortho voltage
97024	Application of a modality to one or more areas; diathermy (eg, microwave)
97139†	Unlisted therapeutic procedure (specify)
97799†	Unlisted physical medicine/rehabilitation service or procedure
97810	Acupuncture, one or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
97811	Acupuncture, one or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)
97813	Acupuncture, one or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
97814	Acupuncture, one or more needles; with electrical stimulation; initial 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)
0019T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed

†**NOTE**: **Experimental, investigational, unproven and not covered when used to report laser therapy or other non-covered modality outlined above for the treatment of plantar fasciitis.**

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

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