Medical Coverage Policy

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Plantar Fasciitis Treatments

Table of Contents

Related Coverage Resources

Acupuncture
Autologous Platelet-Derived Growth Factors (Platelet-Rich Plasma [PRP])
Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions
Orthotic Devices and Shoes
Low-Level Laser and High-Power Laser Therapy
Peripheral Nerve Destruction for Pain Conditions
Physical Therapy
Tissue-Engineered Skin Substitutes

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Overview

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

Coverage Policy

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

Each of the following is considered Not Medically Necessary for the treatment of plantar fasciitis:

- radiotherapy
- stem cell therapy
- stereotactic radiofrequency thermal lesioning

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

- amniotic-derived allografts (e.g., human amniotic membrane injections)
- autologous platelet-derived growth factors
- coblation® (e.g., Topaz™)
- extracorporeal shock wave therapy (ESWT)
- intracorporeal pneumatic shock therapy (IPST)
- percutaneous ultrasonic ablation (e.g., Tenex Health TX®)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Not Medically Necessary for the treatment of plantar fasciitis:

CPT®* Codes	Description
28899†	Unlisted procedure, foot or toes
38230	Bone marrow harvesting for transplantation; allogeneic
38232	Bone marrow harvesting for transplantation; autologous
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38241	Hematopoietic progenitor cell (HPC); autologous transplantation

Effective 5/15/2026

CPT®* Codes	Description
77401	Radiation treatment delivery, superficial and/or ortho voltage, per day (Code deleted 12/31/2025)

†**Note: Considered Not Medically Necessary when used to report the injection of stem cells and stereotactic radiofrequency thermal lesioning.**

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

CPT®* Codes	Description
28890	Extracorporeal shock wave, high energy, performed by a physician or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia
28899††	Unlisted procedure, foot or toes
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed

HCPCS Codes	Description
Q4100	Skin substitute, not otherwise specified
Q4139	AmnioMatrix or BioDMatrix, injectable, 1 cc
Q4155	Neox Flo or Clarix Flo 1 mg
Q4174	PalinGen or ProMatrX, 0.36 mg per 0.25 cc
Q4192	Restorigin, 1 cc
Q4215	Axolotl ambient or axolotl cryo, 0.1 mg

††**Note: Considered Experimental/Investigational/Unproven when used to report, coblation® (e.g., Topaz™), intracorporeal pneumatic shock therapy (IPST) or Percutaneous ultrasonic ablation (e.g. Tenex Health TX®)**

General Background

Plantar fasciitis is an overuse injury resulting in inflammation of the plantar fascia, a thick fibrous band 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. Race and ethnicity is not significant in the incidence of plantar fasciitis (Young, 2023). 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. 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).

Evidence on the effectiveness of steroid injections in reducing pain in patients with plantar fasciitis includes systematic reviews of randomized and quasi-randomized controlled trials (Whittaker, et al., 2019; 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 (Buchbinder, 2022). 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).

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.

Amniotic-Derived Allografts: Amniotic-derived allografts are harvested from human placenta tissue soon after birth and processed into injectable solutions that are hypothesized to reduce inflammation and enhance healing when injected into soft tissue such as the plantar fascia.

U.S. Food and Drug Administration (FDA): Amniotic membrane is a banked human tissue regulated by the American Association of Tissue Banks® (AATB) and does not require FDA approval. However, the manufacturer must meet specific FDA regulations for the collection, processing, and selling of human cell, tissue, and cellular and tissue-based products (HCT/Ps) (FDA, 2024).

Literature Review Amniotic-Derived Allografts:

Cazzell et al. (2018) conducted a multicenter, randomized controlled trial (n=145) to investigate the safety and effectiveness of a micronized dehydrated human amnion/chorion membrane (dHACM) injection (Amniofix) for the treatment of plantar fasciitis (PF). Inclusion criteria were: age 21 to < 80 years; confirmed diagnosis of PF for 1–18 months; VAS pain sale of ≥ 45 at time of randomization; and had undergone conservative treatment for ≥◦30 days (rest, ice, compression, and elevation [RICE]; stretching exercises; nonsteroidal anti-inflammatory drugs [NSAIDs] and/or orthotics). Patients were excluded if they had trauma or previous surgery to the affected area; bilateral PF; prior use of lower limb injection therapy; diabetes and multiple other comorbidities and contraindications. Patients were randomized to receive one injection of Amniofix (n=73) or sodium chloride placebo (n=72). The primary outcome was the mean change in the visual analog scale (VAS) score between baseline and three months post-injection. Secondary outcome was mean change in Foot Function Index–Revised (FFI-R) score between baseline and three months follow-up. Overall, at the three month follow-up, 60 subjects in the treatment group compared to 34 control subjects reported at least a 50% reduction in VAS scores from baseline. VAS scores in the treatment group were 76% lower compared with a 45% reduction in mean VAS scores for controls ($p<0.0001$). Compared to baseline the FFI-R scores for treatment subjects showed a significant mean reduction ($p=0.0004$) of 60% compared to a 40% reduction in the control group at the three month follow-up. Control group subjects reported a reduction in pain and improved function over time. No serious adverse events were related to the study. Two cases of post-injection pain at the injection site and one case of post-injection itching were considered normal events. Limitations of the study include the small patient population and short-term follow-up. It is unknown if additional injections would be effective for persistent symptoms. Three Amniofix and two control subjects did not complete the three month follow-up and the last observation data was carried forward to the three-month analysis.

Hanselman et al. (2015) conducted a randomized, controlled, double-blind, single-center pilot study that compared cryopreserved human amniotic membrane (c-hAM) to corticosteroid injection. Patients (n=24) were randomized into one of two treatment groups: c-hAM injection (n=9) using AM3 (now known as Clarix®) or corticosteroid injection (n=14) using Depo Medrol. The groups received an injection of c-hAM or corticosteroid injection at their initial baseline visit with an option for a second injection at their first six-week follow-up. Adults aged 18–65 years with plantar fasciitis were included if symptoms were present for a minimum of three months but less than one year, and without coexisting foot or ankle pathology. The primary outcome was the measurement of foot health and impact on quality of life using the Foot Health Status Questionnaire (FHSQ). The secondary outcomes measured were pain using the Visual Analog Scale (VAS) and verbally reported percentage improvement. Follow-up was obtained 12 weeks after the most recent injection. A total of 96% of the patients completed the required 12 weeks of follow-up and were included in the analysis. One subject was lost to follow-up. Three patients in each group received second injections. In the one injection group, shoe fit at six weeks ($p=0.0244$) and general health at six weeks ($p=0.0132$) were statistically greater in the corticosteroid group. In the two injection group, foot pain score at 18 weeks ($p=0.0113$) was statistically greater in the c-hAM group, indicating an improvement in foot pain. All other variables resulted in no significant difference. Verbal percentage improvement at 12 weeks ($p=0.041$) was statistically greater in the one injection steroid group. There were no adverse side effects experienced. Author noted limitations included: small patient population, short term follow-up,

drug formulation was changed during the study and the risk of bias as patients were recruited through community and institutional advertising. The authors concluded that cryopreserved hAM injection may be safe and comparable to corticosteroid injection for treatment of plantar fasciitis. The authors stated that this is a pilot study and further investigation is required.

There is insufficient evidence in the published peer-reviewed medical literature to support the use of amniotic-derived allograft 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 (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 combine 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.

U.S. Food and Drug Administration (FDA): The Center for Biologics Evaluation and Research (CBER) regulates the collection of blood and blood components used for transfusion. The systems used for preparing autologous platelet-derived growth factors are FDA approved under the 510(k) process. In general, the systems are approved to be used at the patient's point of care and/or in a clinical laboratory to prepare autologous platelet-rich plasma/platelet concentrate from the patient's own blood (FDA, 2025).

Literature Review Autologous Platelet-Derived Growth Factors: Aleid et al. (2025) conducted a systematic review and meta-analysis to compare platelet-rich plasma injections with corticosteroid injections for chronic plantar fasciitis. The systematic review included eight randomized controlled trials involving 599 participants. Interventions compared were platelet-rich plasma injections versus corticosteroid injections, with pain measured using the Visual Analog Scale and function measured using the American Orthopaedic Foot & Ankle Society score. Studies meeting the following criteria were included: adults diagnosed with chronic plantar fasciitis with outcomes reported for Visual Analog Scale and American Orthopaedic Foot & Ankle Society. Studies focusing on pain other than heel pain, using interventions beyond platelet-rich plasma or corticosteroid injections, lacking clear outcomes, or non-clinical designs were excluded. Follow-up periods across included studies ranged from 3 to 36 months. Subjects lost to follow-up were not reported for the pooled analysis. Outcomes for pain demonstrated that a common-effects model favored platelet-rich plasma (mean difference 0.7166), whereas the random-effects model showed no significant difference (mean difference 0.4657) and high heterogeneity (I^2 90.5%; Q-test $p < 0.0001$). Functional outcomes demonstrated significant improvement favoring platelet-rich plasma (mean difference 16.1302; 95% confidence interval 14.7091–17.5513). Diagnostic accuracy metrics (negative predictive value, positive predictive value, sensitivity, specificity) were not reported. Adverse events were narratively described, with minor infections in both groups and more side effects (for example, skin changes and fat atrophy) in the corticosteroid group; no significant complications were reported. Limitations included variability in methodologies and patient characteristics, variability in platelet-rich plasma preparation, short follow-up durations, small sample sizes, and limited generalizability. The authors concluded that platelet-rich plasma demonstrates superior functional improvement and potentially better long-term pain relief than corticosteroid injections and recommended additional high-quality randomized controlled trials with standardized protocols.

A systematic review and meta-analysis by Zuo et al. (2025) evaluated the comparative efficacy of platelet-rich plasma (PRP) versus corticosteroid (CS) injections in the treatment of plantar fasciitis, incorporating 24 randomized controlled trials (RCTs) with a total of 1,653 adult participants. Each study included PRP and CS arms, with PRP administered in volumes ranging from 2 to 5 mL and CSs including methylprednisolone, triamcinolone, betamethasone, or dexamethasone. Inclusion criteria required adult patients with plantar fasciitis unresponsive to at least 3 months of conservative therapy, and studies reporting outcomes on pain (visual analog scale [VAS]), foot function (American Orthopedic Foot and Ankle Society [AOFAS] scores), and Page 16 of 40 Medical Coverage Policy: 0507 plantar fascia thickness. Exclusion criteria included animal studies, non-original research, abstracts only, and patients with confounding foot or ankle pathologies. The results reveal that while PRP injections do not demonstrate superior outcomes compared to corticosteroids in the short term (one month, VAS $p = 0.12$; AOFAS $p = 0.31$) or at 12-month follow-up (VAS $p = 0.08$; AOFAS $p < 0.001$), they provide significantly greater pain relief and functional improvement in the medium term (3–6 months), as evidenced by lower VAS scores ($p = 0.03$ at three months; $p < 0.001$ at six months) and higher AOFAS scores ($p = 0.05$ at three months; $p < 0.001$ at six months). No significant differences were observed in plantar fascia thickness at any time point. Limitations include high heterogeneity ($I^2 > 90\%$ in most analyses), lack of standardization in PRP preparation (e.g., platelet concentration, use of activators), inconsistent blinding, and variability in CS formulations. These findings suggest PRP may offer superior medium-term pain and functional outcomes, but its long-term efficacy and reproducibility remain uncertain, limiting its support as a covered non-surgical intervention without further high-quality, standardized trials.

Atzmon et al. (2022) conducted a randomized, prospective trial that compared the efficacy of platelet-rich plasma (PRP) to partial plantar fasciotomy (PPF) surgery in patients with chronic plantar fasciitis (CPF). Patients diagnosed with recurrent CPF following conservative treatment for at least three months prior to treatment were included in the study. Patients (n=32) were randomly divided into two groups, a PRP treatment group (n=16), and a PPF group (n=16). Outcomes assessed pain and the limitations of activity using the Roles-Maudsley Scale (RM) and the Visual Analog Score (VAS). The outcomes were assessed during the preoperative visit and three, six, and 12 months postoperatively. All patients in both groups received the same post-treatment protocol, except for heel-raising insoles that were not allowed in the plantar fasciotomy group. Both procedures showed a reduction in RM scores during the follow-up year (9 to 1.62 for PPF and 8.7 to 2.4 for PRP). However, patients in the PPF group had significantly lower Roles-Maudsley Scale (RM) scores compared to the PRP group one-year after treatment ($p<0.0001$). In addition, there was a significant difference in terms of change from preoperative to postoperative RM score, favoring the PRP group ($p<0.0001$). There was no significant change in VAS pain between the two groups ($p=0.366$). Author noted limitations included the small patient population and short term follow-up. No health disparities were identified by the investigators.

Vellingiri et al. (2022) conducted a prospective study assessed the efficacy, safety, side effects and complications of a local injection of platelet-rich plasma (PRP) compared to a corticosteroid (CS) injection (methylprednisolone) in the treatment of plantar fasciitis. Adults (n=110) who were diagnosed with plantar fasciitis for more than three months' duration and had failed conservative management methods, had Visual Analog Scale (VAS) pain was more than six and the patients with plantar fascia thickness > 5 mm when assessed by ultrasound were included in the study. Patients were assigned into two groups, PRP injection (n=55) and CS (n=55) methylprednisolone injection. Following the administration of injections, the patients' clinical, radiological, subjective and functional outcomes were assessed at the first, third and sixth month by using the Visual Analog Scale (VAS), Foot and Ankle Outcome Instrument Core Scale (FAI), Roles and Maudsley Scores (RMS), American Orthopaedic Foot and Ankle Society (AOFAS) ankle-hind foot scale and ultrasound of plantar fascia thickness. Ten patients were lost to follow-up and two patients had post-operative complications (superficial infection) in the PRP injection group, while ten patients

had post-procedure complications (five patients developed superficial infections, three patients developed skin depigmentation, and two patients had atrophy of fat pad) in the corticosteroid injections (CSI) group. Infections subsided in all the patients as observed during subsequent follow-up. In the PRP injection group there was significant improvement at the first, third and sixth month in the VAS, AOFAS score and the measurement of the plantar fascia thickness (all $p<0.001$). The FAI score was statistically significant between groups, in favor of the PRP group in the third and sixth month ($p<0.001$). The rating of the Roles and Maudsley score was not measured for statistical significance, however the results were better in the PRP group compared to the CS group at three and six months. The study reported that significant improvement was seen in the PRP injection group when compared with the CSI group, although steroid injections show significant improvement in clinical, subjective rating, functional and radiological outcomes one month after injection. However, PRP injection gives better results in clinical, subjective rating, functional and radiological outcomes during six months when compared to the corticosteroid group. The author acknowledged study limitations included the small patient population, short-term follow-up and lack of a control group. An additional study limitation is that the population only included patients in India and the results may not be applicable to other races or ethnic group In conclusion, the authors stated that in order to provide a clearer insight into the effectiveness of both treatment types, a randomized controlled trial with a larger population, a longer follow-up, and a control group is needed.

Kandil et al. (2020) conducted a prospective, single-blinded, randomized controlled trial (RCT) that evaluated the efficacy and safety of allogeneic growth factors (GF) injection compared to placebo in patients with plantar fasciitis. Patients (n=150) were included in the study if they were age ≥ 20 years with plantar fasciitis. The patients were randomly placed into two groups: a treatment group (n=75) where each patient received a single local injection of allogeneic GFs, and a control group (n=75) where each patient received a single local injection of normal saline 0.9% as a placebo. All the patients were assessed for pain using visual analog scale (VAS) and functional improvement using the Foot Function Index–Revised short form (FFI-Rs) preinjection and at one, three, six, and 12 months postinjection. The primary and secondary outcomes measured the change the VAS score and the FFI-Rs between preinjection and at the three month follow-up, respectively. Additionally, patients were questioned about their satisfaction and adverse effects were recorded. At baseline, there was no statistically significant difference between the two groups regarding the mean VAS score ($p=0.45$) and the mean FFI-Rs score ($p=0.79$). At the three month follow-up, there was a significant reduction in the mean VAS score between the groups, in favor of the treatment group ($p<0.001$). At the 6- and 12-month follow-ups, the mean VAS score was 1.3 and 1.4 in the treatment group and 3.8 and 3.6 in the control group, respectively. At the three month follow-up, there was a significant reduction in mean FFI-Rs score in the treatment group compared to the control group ($p<0.001$). At the 6- and 12-month follow-ups, the mean FFI-Rs score was 21.4 and 21.7 in the treatment group and 33.5 and 32.6 in the control group, respectively. The patients' satisfaction was 92% (either completely or with reservations) in the treatment group, and 78.2% in the control group. Five patients in the treatment group experienced mild postinjection pain, which resolved within 2–4 days. No other adverse effects related to the procedure were reported. Author noted limitations included the lack of comparator group receiving an additional therapy, ultrasonography was not done to guide injections or assess the thickness of the plantar fascia before and after the procedure and a single injection was given to the patients and it is unknown if repeated injections are beneficial. Additional limitations include the short term follow-up, small patient population and population studied only included Egyptians and the results may not be applicable to other races or ethnic groups. The authors concluded that allogeneic GFs injection in patients with plantar fasciitis is effective and safe. However, additional studies are needed to evaluate their adverse effects, immunogenicity, and microbiological safety.

Khurana et al. (2020) conducted a randomized control trial that compared the effectiveness of PRP and methylprednisone when injected in patients with plantar fasciitis who had failed conservative

management. Adults (n=118) diagnosed with plantar fasciitis and refractory pain following four weeks of conservative treatment were enrolled in the study. Patients were randomized into two groups: Group A (n=58) received an injection of platelet rich plasma (PRP), and Group B (n=60) received an injection of corticosteroid. All patients underwent conventional radiographs and magnetic resonance imaging (MRI) of the involved foot to rule out stress fractures, associated bone lesions or other causes of plantar heel pain. Patients were assessed for pain on the day of presentation and then after therapy at two weeks, four weeks, three months, and six months using the Visual Analog Scale, and AOFAS hind-foot Score was taken at the six month follow-up. Both groups experienced a significant improvement of VAS ($p<0.001$). The maximum change from the pre-injection value was observed at the 6 months. There was a significant difference between the groups in terms of AOFAS Score at six months ($p<0.001$), with the mean AOFAS Score being higher in the PRP group. The limitations of the study included the unblinded study design, small patient population and short-term follow-up. Additionally, the present study may be underpowered as the drop-out rate was greater than the initial allowance of 15%. No health disparities were identified by the investigators.

Tabrizi et al. (2020) conducted a single-blind, randomized controlled trial that investigated the efficacy of platelet-rich plasma (PRP) injection compared to local corticosteroid injection in obese patients with chronic plantar heel pain (CPHP). Obese patients (n=32) with chronic plantar heel pain were randomly allocated to two groups; group 1 (n=16) received an injection of 40mg dimethylprednisolone into the painful heel, whereas group 2 (n=16) received three separate injections of PRP, with each injection administered one week apart. Patients with obesity (BMI ≥ 30 kg/m2) and failure of conservative treatment for a minimum of two months were eligible for inclusion in study. The outcomes measured pain severity response using the VAS scale and patient function using the Foot Function Index (FFI). Morning and daily pain of the patients was recorded before the injection, and the pain severities of the patients were evaluated at eight, 12, and 24 weeks after treatment. Symptom return and recurrence were determined within six months of follow-up. The groups were compared at baseline and at 24 weeks after the injection, or course of injections, was administered. One patient was lost to follow-up, therefore, 31 (96.9%) of those treated were included in the analyses. In the corticosteroid-treated group, 11 patients received bilateral injection. In the PRP treated group, nine patients received bilateral injection. There was no significant differences in morning and total pain severities or FFI between the groups at baseline. At 24 weeks following treatment, final pain and morning pain scores along with mean foot function index scores were statistically significant in patients treated with corticosteroid compared to those treated with PRP ($p<0.001$ and $p<0.001$, respectively). Author noted limitations included: treatments were likely influenced by concomitant use of oral NSAID medication and other adjunct therapies, plantar calcaneal spurs were not identified, not all patients had bilateral heel pain, and three weekly injections of PRP were done compared with one injection of corticosteroid. The authors concluded that pain reduction and functional improvement were better in the corticosteroid-treated group compared to the PRP-treated group at six months after the course of injection therapy.

Keene et al. (2019) conducted a placebo controlled, multi-center, two arm, parallel group, superiority randomized controlled trial (PATH-2) to determine the clinical efficacy of platelet rich plasma in treating acute, non-surgically managed rupture of the Achilles tendon. Patients were included in the study if they were age ≥ 18 years; had a clinical diagnosis of a complete acute mid-substance rupture of the Achilles tendon; were within 12 days of injury; were able to walk unaided pre-injury; and were being managed non-surgically by immobilizing the ankle in a cast, splint, or boot. Patients (n=230) were randomized 1:1 to platelet rich plasma (n=114) or placebo (dry needle; n=116) injection. All participants received standard rehabilitation care (ankle immobilization followed by physiotherapy). Primary outcome measured muscle tendon function at 24 weeks using the validated heel rise endurance test. Secondary outcomes were measured at four, seven, 13 and 24 weeks and included patient reported function (Achilles tendon rupture

score), quality of life (short form 12 version 2®), pain (visual analogue scale), goal attainment (patient specific functional scale), and adverse events. At 24 weeks, 202 (88%) participants completed the heel rise endurance test and 216 (94%) of the patient reported outcomes. No difference was detected in muscle tendon function between participants receiving platelet rich plasma injections and those receiving placebo injections or in any secondary outcomes or adverse event rates. Author noted limitations included different volumes of whole blood were taken from the two randomization groups (55 mL platelet rich plasma/5 mL placebo) and participant masking could have been compromised. The authors concluded that there is no evidence that platelet rich plasma when compared to placebo can improve objective muscle tendon function, patient reported function, or quality of life after acute Achilles tendon rupture.

Peerbooms et al (2019) conducted a randomized controlled trial to determine the effectiveness of PRP compared to corticosteroid injections for chronic plantar fasciitis. Patients (n=115) with chronic plantar fasciitis were allocated to have a steroid injection (n=52) or PRP (n=63). Included patients were age 18 years and older with plantar fasciitis (at least six months' duration) and failed nonoperative treatment. Patients were able to understand the informed consent with the morning Foot Function Index (FFI) Pain score at 5 (0-10 scale). The primary outcome measure was the Foot Function Index (FFI) pain score. Secondary outcome measures were function scored by the FFI Activity, FFI Disability and American Orthopaedic Foot & Ankle Society, along with quality of life, as scored with the short version of the World Health Organization Quality of Life (WHOQOL-BREF). All outcomes were measured at baseline and at four, 12, and 26 weeks and one year after the procedure. Thirty-Three patients were lost to follow-up, and the outcomes were reported on the patients (n=82) that completed the study (n=46/PRP group; n=36/corticosteroid group). In the corticosteroid group, FFI Pain scores decreased quickly and then remained stable during follow-up. In the PRP group, FFI Pain reduction was more modest but reached a lower point after 12 months than the control group. After adjusting for baseline differences, the PRP group showed significantly lower pain and disability scores at the one-year follow-up than the control group (p=0.012 and p=0.016, respectively). The number of patients with at least 25% improvement (FFI Pain score) between baseline and 12-month follow-up differed significantly between the groups. Of the 46 patients in the PRP group, 39 (84.4%) improved at least 25%, while 20 (55.6%) of the 36 in the corticosteroid group showed such an improvement (p=0.003). Author noted limitations included a violation of protocol, 16 patients were treated with a 30mL PRP kit instead of the 60mL PRP kit as described in the protocol. Second, ultrasound-guided injections were not used for both groups. A final limitation is the lack of data on the characteristics between the study group and the eight patients who were not suitable for further allocation, potentially leading to bias. The authors concluded that treatment of patients with chronic plantar fasciitis with PRP seems to reduce pain and increase function more as compared with the effect of corticosteroid injection. However, future decisions for the application of PRP for PF should be confirmed by further follow-up from this study.

Shetty et al. (2019) conducted a three-arm randomized controlled trial that compared platelet rich plasma (PRP) with corticosteroid (CS) and placebo for the treatment of chronic plantar fasciitis with regard to pain and function. Patients (n=90) were blindly randomized into three groups, PRP (n=30), CS (n=30), and placebo (n=30). Patients were included in the study if they were age ≥ 18 years with a diagnosis of chronic plantar fasciitis who had failed conservative treatment for ≤ 3 months. The PRP group received 2 mL of PRP mixed with 1 mL of 1% lidocaine; the CS group received 2 mL of methylprednisolone acetonide (40 mg/mL) mixed with 1 mL of 1% lidocaine; and the placebo group received 2 mL of 0.9% normal saline mixed with 1mL of 1% lidocaine. The outcomes measured pain, function and general health. All patients were followed at one week, three weeks, and three, six, 12, and 18 months using a self-developed item set for demographic data and validated tools to assess pain (visual analog scale [VAS]), function (Roles and Maudsley [R&M] score) and general health (Short Form 12 Health Survey [SF-12]). All patients completed their follow-up visits. All groups had significant improvement in VAS scores, the R&M score and

the SF-12 score between preinjection and the 18-month follow-up. The corticosteroid group demonstrated the greatest improvement in VAS scores and the R&M score during the first three weeks. The PRP group demonstrated significant improvement in the VAS scores (p=0.05/six months; p=0.01/12 months; p=0.005/18 months) and the R&M score (p=0.05/12 months; p=0.05/18 months) during the 3–18-month follow-up period. Clinical significance was not reached for the SF-12 score in the 3–18-month follow-up period. No patients suffered any complication (local or systemic). The author noted limitations were the self-bias of measuring own results and the institutional bias of producing PRP.

Soraganvi et al. (2019) conducted a double-blind, randomized controlled trial that compared the efficacy of PRP and steroid injection in the treatment of chronic plantar fasciitis and analyzed the effect on the thickened plantar fascia. Patients with a clinical diagnosis of chronic plantar fasciitis after failed conservative treatment and plantar fascia thickness more than 4mm were included in the study. Patients (n=60) were randomized into two groups, Group A (n=30) received a PRP (3ml) injection and Group B (n=30) received a steroid injection (Depomedrol 80mg (2ml) + 0.5ml xylocaine 2%). All patients in both groups were advised on plantar fascia stretching exercise. The outcomes measured pain and function using the visual analog scale (VAS) and the American Orthopedic Foot and Ankle Society (AOFAS) score. Assessment was done before injection, at six weeks, three months and six months follow-up after injection. Plantar fascia thickness was assessed before the intervention and six months after treatment using sonography. Three patients were lost to follow-up, and the results were analyzed using 57 patients. The mean VAS score in Group A was statistically significant when compared to Group B at six weeks, three months and six months ($p<0.007$, $p<0.001$ and $p < 0.001$, respectively). At six months, the AOFAS score and the reduction in the thickness of plantar fascia were clinically significant in group A compared to Group B ($p<0.001$, $p<0.0003$, respectively). An author noted limitation was the variability of platelet concentration due to the lack of standardization in preparation, concentration and dosage of platelets. The authors concluded that local injection of platelet-rich plasma is an effective treatment option for chronic plantar fasciitis when compared with steroid injection with long lasting beneficial effect. However, further basic research is necessary for understanding the exact mechanism of action of PRP.

Jain et al. (2018) conducted a prospective randomized that compared the efficacy of corticosteroids and platelet rich plasma (PRP) in the treatment of plantar fasciitis. Patients (n=80) were randomly allocated into two groups of 40 each (group A and group B). Patients were treated with local corticosteroid injection in group A and autologous PRP injection in group B. Included patients were diagnosed with plantar fasciitis with failure of conservative treatment (stretching exercises, nonsteroidal anti-inflammatory drugs, and heel pads) for at least three months, a pain level higher than five on the visual analog scale and the ability to understand the informed consent. Primary outcomes included pain scores using the visual analog scale (VAS), subjective evaluation of the outcome of the procedure (modified Roles and Maudsley score), functional outcomes (FAI core scale and AOFAS ankle-hindfoot score) and the thickness of the plantar fascia using ultrasonography. They were assessed at baseline with follow-ups occurring after the injection at one month, three months, and six months. Post-injection, there was significant improvement in pain, patient evaluation of the procedure outcome and functional outcomes in both groups. The thickness of the plantar fascia post-injection reduced significantly in the steroid group as compared to the PRP group at the one month and three month follow-up (p=0.004 and p=0.011, respectively). At the six month follow-up the difference in thickness between the two groups became statistically insignificant (p=0.148). There were no reported complications from PRP or corticosteroid injections. Author noted limitations included small patient population, short term follow-up, unblinding and the lack of a control group. The authors concluded that the treatment of plantar fasciitis with steroid or PRP injection was equally effective.

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.

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.

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.

U.S. Food and Drug Administration (FDA): 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 (FDA, 2016).

Literature Review

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.

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 two types of ESWT are focused and radial. Focused ESWT (fESWT) 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 (Chou, et al., 2024). The difference between the three methods of generation is the time at which the shockwave forms (Roerdink, et al., 2017).

Radial shock wave delivery (rESWT) utilizes a ballistic device to transmit energy over a broad area, resulting in a more superficial distribution within the tissue than fESWT (Chou, et al., 2024). This process generates stress waves in the applicator, which then transmit pressure waves—known as radial shock waves—non-invasively into the tissue. Because the waves produced 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). Nevertheless, published literature continues to refer to radially generated wave therapy as radial ESWT.

U.S. Food and Drug Administration (FDA):
Extracorporeal shock wave therapy devices (focal and radial) are considered Class III medical devices and regulated by the FDA through the Premarket Approval (PMA) process. They are indicated for non-surgical treatment of chronic proximal plantar fasciitis in adults with symptoms lasting ≥6 months that have not responded to conservative therapy (FDA, 2025).

Effective 5/15/2026

Device or Product	Identifier	Manufacturer	Decision Date
OssaTron®	P990086	HealthTronics, Inc.	10/12/2000
Epos™ Ultra	P000048	Dornier Medical Systems, Inc.	1/15/2002
Orthospec™	P040026	Medispec, Ltd.	4/01/2005
Orbasone Pain Relief System	P040039	Orthometrix, Inc.	8/10/2005
EMS Swiss DolorClast®	P050004	Electro Medical Systems S.A.	5/08/2007
Storz Medical Duolith SD1 Shock Wave Therapy Device	P080028	Storz Medical AG	1/08/2016

*FDA product codes: NBN

Note: Device or product names are provided for example purposes only. Their inclusion does not indicate endorsement or preference for any specific brand or model. Coverage decisions are not based solely on FDA approval. This list is not intended to reflect all available products or technologies.

Literature Review ESWT:
The safety and effectiveness of ESWT for the treatment of plantar fasciitis has been evaluated in technology assessments, systematic reviews with meta-analyses (n=6–11 studies/550–1287 participants), and randomized controlled trials (RCTs) (n=44–272). These studies have compared ESWT to placebo, conservative treatment such as exercise and/or orthotic support or steroid injections with conflicting results. In some studies, there is a greater reduction in heel pain and/or improvements in functional ability in individuals treated with ESWT (Xu, et al., 2020; Mishra, et al., 2019; Xiong, et al., 2019; Lai, et al., 2018; Li, et al., 2018b). However, similar improvement rates for both ESWT treatment and placebo or conservative treatment groups have been reported in other studies (Cinar, et al., 2020; Çağlar Okur and Aydın, 2019; Li, et al., 2018a). In general, these studies have limitations such as small sample sizes, lack of control groups, participant attrition, and short-term follow-up (3–12 months) that limit the generalizability of their results.

Tung et al. (2025) completed a systematic review and meta-analysis of randomized controlled trials (RCTs) (n=15 studies/1123 participants) to evaluate the effectiveness of extracorporeal shock wave therapy (ESWT) versus other conservative treatment options (e.g., corticosteroid injections (CSI), orthotics) or placebo for managing plantar fasciitis (PF). Eligible RCTs compared ESWT to any other treatment modality using at least one of the following primary outcomes: visual analog scale (VAS) pain scores, plantar fascia thickness (PFT) and total Foot Function Index (FFI). Studies with follow-up durations under 12 weeks or insufficient data for effect size calculation were excluded. Follow-up periods ranged from 3 to 24 months. Overall ESWT demonstrated a significantly greater improvement in VAS compared to placebo ($p<0.00001$) and improved FFI significantly more than corticosteroid injections ($p=0.03$). However, custom foot orthotics significantly outperformed ESWT in FFI outcomes ($p=0.001$). No significant differences were found in PFT between ESWT and other treatments. Limitations included heterogeneity across studies, small sample size, and a short-term follow-up.

Heide et al. (2024) conducted a four-arm, parallel-group, sham-controlled, observer-blinded, and partly patient-blinded randomized controlled trial (RCT) to assess the effectiveness of radial extracorporeal shock wave therapy (rESWT) in reducing heel pain in patients with plantar fascipathy. A total of 200 participants between aged 18–70 were randomized into four groups: rESWT (n=50), sham-rESWT (n=50), standardized exercise program (n=50), or advice plus custom foot orthoses (n=50). Inclusion criteria required heel pain lasting more than three months, localized to the medial calcaneal tuberosity, with tenderness on palpation. Exclusion criteria

included recent rESWT treatment, inflammatory or neurological conditions, prior foot/ankle surgery with retained hardware, and contraindications to rESWT (e.g., anticoagulant use, pregnancy, bleeding disorders, epilepsy, or pacemaker). The primary outcome was self-reported heel pain during activity over the past week, measured using a numeric rating scale (NRS). Secondary outcomes included function and quality of life and were assessed via the RAND-12 Health Status Inventory, Foot Function Index Revised Short Form (FFI-RS), and Patient Global Impression of Change (PGIC). Assessments were conducted at baseline and at 3, 6, and 12 months. At six months, no statistically significant differences were found in heel pain reduction between rESWT, sham-rESWT, exercise, or advice plus orthoses. Secondary outcomes similarly showed no significant differences. Reported adverse events included treatment related pain and discomfort across all groups. Study limitations include single center design in specialized care setting, small population, short term follow-up, reliance on self-reported questionnaires, lack of objective testing, and potential conflict of interests.

Gezginaslan, et al. (2021) compared the effectiveness of density and number of sessions of extracorporeal shock wave therapy (ESWT) in plantar fasciitis (PF) patients in a double-blind, prospective, randomized-controlled study. A total of 94 patients with the diagnosis of PF were included in the study. All patients were randomly divided into three groups. Group 1 (n = 33) received a total of seven sessions of high-energy flux density (H-ESWT) (0.26 mJ/mm2); Group 2 (n = 31) received a total of three sessions of H-ESWT (0.26 mJ/mm2); Group 3 (n = 30) received total of seven sessions of low-energy flux density (< 0.08 mJ/mm2) with three days interval. At baseline and one month after the treatment, the Visual Analog Scale (VAS), Short Form-36, Foot Function Index (FFI), Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Scale, and Six-Minute Walking Test (6MWT) scores were compared among the groups. Of the patients, 69 were females and 25 were males with a mean age of 45.0 ±8.43 (range, 25-67) years. There were no statistical differences in the age, sex, demographic characteristics, and baseline VAS, FFI, 6MWT, and FACIT scores between the groups ($p > 0.05$). However, there was a statistical decrease in the VAS, FACIT, and FFI scores in all groups after treatment compared to baseline, although only the 6MWT, and Short Form-36 subscale scores were statistically higher ($p < 0.05$). There was also a statistical difference in the scale scores in Group 1 versus Group 2; and in Group 2 versus Group 3. Per the authors, the study results suggest H-ESWT for a high number of sessions is more effective than L-ESWT for a low number of sessions in regard to pain, quality of life, physical function, fatigue, and disability in patients with PF. The short-term follow-up (one month) did not allow for assessment of intermediate and long-term outcomes. A small sample size (n = 94) makes it difficult to determine whether these conclusions can be generalized to a larger population. Further investigation is needed before clinical usefulness of this procedure is proven.

ESWT for the treatment of plantar fasciitis 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.

Literature Review IPST: 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.

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. 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 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).

Literature Review Percutaneous Ultrasonic Ablation: 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).

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

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.

Literature Review Radiotherapy: 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 aged 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.

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

Stem Cell Therapy: Stem cell therapy refers to mesenchymal stem cells harvested from bone marrow, adipose tissue, amniotic membrane, peripheral blood and/or synovial tissue. Stem cells are cells that have the ability to differentiate into a number of various cell types and are being used more frequently in the treatment of orthopedic and/or musculoskeletal conditions. There are various types of stem cells which include but are not limited to embryonic, mesenchymal, and hematopoietic. Embryonic stem cells are isolated from embryonic tissue, while both mesenchymal and hematopoietic are isolated using adult bone marrow. While some stem cells are restricted to a few lineages, others may differentiate into a wide variety of cell types. Hematopoietic stem cell transplantation is the only stem cell therapy well-established in clinical practice (Gepstein and Skorecki, 2020).

Within orthopedics, mesenchymal stem cells are derived mainly from bone marrow, however other sources include adipose tissue (i.e., lipoaspirate), umbilical cord tissue, amniotic fluid, and other extra-articular sources. Mesenchymal stem cells (MSCs) are adult-derived, undifferentiated, multipotent cells that express a variety of different cell surface proteins and can differentiate into a variety of lineages, such as adipogenic (fat cells), osteogenic (bone cells), and chondrogenic (cartilage cells). Adult MSCs do not reach pluripotency, pluripotency is the ability to differentiate into all cell types derived from three germ layers (i.e., ectoderm, mesoderm, endoderm) of the developing embryo (e.g., embryonic stem cell). If MSCs are placed within normal healthy bone, cartilage, or adipose tissue, the stem cells differentiate into that particular tissue. In theory, this property applies to all mesenchymal tissues, including muscle, tendon, and fibrous tissues. MSCs demonstrate little to no ability however to differentiate into nonmesenchymal tissue (e.g., neural or hepatic cells) (Cook and Young, 2022).

U.S. Food and Drug Administration (FDA): Medical and surgical procedures do not require FDA approval. In addition, the use of concentrated, autologous mesenchymal stem cells (MSCs) do not require FDA approval. The FDA does regulate human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation, title 21, parts 1270 and 1271. Currently there are no allogenic MSC materials using engineered or expanded MSCs approved by the FDA for orthopaedic applications (Cook and Young, 2022). According to the FDA, "the only stem cell-based products that are FDA-approved for use in the United States consist of blood-forming stem cells (hematopoietic progenitor cells) derived from cord blood." Safety concerns of the FDA regarding the use of unproven stem cells include administration site reactions, failure of cells to work as expected, the growth of tumors, and the ability of cells to move from placement sites and change into inappropriate cell types and multiply (FDA, 2020b).

Literature Review Stem Cell Therapy: Areas undergoing current investigation for the application of MSCs include but are not limited to regeneration and/or repair of musculoskeletal tissue, for example muscle, tendon, and fibrous tissues. There is a lack of evidence supporting the efficacy of this modality in the treatment of plantar fasciitis Therefore, the procedure is considered unproven 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.

Professional Societies/Organizations

American Academy of Orthopaedic Surgeons (AAOS): The AAOS does not take a position for or against the use of stem cell therapy for orthopaedic applications, however within a position statement regarding the use of emerging biologic therapies (AAOS, 2020) the AAOS stated the following: "Surgeons must be aware of the scientific basis for the different treatment options offered to their patients, including benefits and risks. Not all biologic products require extensive FDA regulation, and in some cases, the FDA has primarily focused on safety concerns and has ceded responsibility for determining the efficacy of these products to the clinician."

"The American Academy of Orthopaedic Surgeons (AAOS) believes that surgeons should be cognizant of the risks, benefit, regulatory status and labeled indications of the products they use. "For all products, but particularly those which the FDA does not critically evaluate effectiveness data, clinicians bear a greater responsibility to independently weigh that evidence. This responsibility also extends to off-label use of FDA-regulated products, and cases where the devices used to create or deliver the biologic product, rather than the product itself, are what has been approved by the FDA." The statement concluded that "the clinicians using these biologic products need to be particularly careful to weigh the available evidence and conduct shared decision-making with the patient in the informed consent process." (AAOS, 2020).

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).

International Society of Stem Cell Research (ISSCR): The ISSCR published information regarding stem cell types and uses (ISSCR, 2021) and asserts there is little evidence they are beneficial. Mesenchymal stem cell (MSC) therapy remains in early experimental stages. According to ISSCR, MSC are cells that originate from stroma, the connective tissue surrounding tissues and organs. Although various MSCs are thought to have stem cell and immunomodulatory properties as treatment for various disorders. Scientists do not fully understand whether these cells are actually stem cells or what types of cells they are capable of generating. They do agree that not all MSCs are the same, and that their characteristics depend on where in the body they come from and how they are isolated and grown. Some types of stem cells are capable of migration after transplantation, meaning there is a risk of off-target effects and inappropriate integration.

Washington State Health Care Authority (WSHCA): In 2017 the WSHCA conducted a technology assessment that evaluated the comparative efficacy, effectiveness, and safety of ESWT in adults for the treatment of various musculoskeletal and orthopedic conditions, including but not limited to plantar fasciitis, tendinopathies, adhesive capsulitis of the shoulder, and subacromial shoulder pain. As part of the technology assessment a total of 72 randomized controlled trials were included and reviewed. Limitations of the studies noted by the Committee generally included potential for risk bias, short-term follow-up, inconsistency of measured outcomes, and lack of high quality evidence and small sample sizes. The authors concluded that extracorporeal shock wave therapy was unproven for efficacy and cost-effectiveness.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

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Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	• Revised policy statement for not medically necessary treatments for plantar fasciitis	5/15/2026

	• Revised policy statement for experimental, investigational or unproven treatments for plantar fasciitis	
Annual Review	No clinical policy statement changes.	02/15/2025
Focused Review	Removed policy statements for: laser therapy (low-level laser therapy/LLLT); coblation® (e.g., Topaz™); electron-generating devices; low-load prolonged-duration stretch (LLPS) devices (e.g., Dynasplint System®, Ultraflex, Pro-glide™ Dynamic ROM, Advance Dynamic ROM®); microwave diathermy; trigger-point needling and infiltration of the proximal medial gastrocnemius muscle	12/15/2024
Annual Review	No clinical policy statement changes.	02/15/2024