

Molina Clinical Policy

Plantar Fasciitis Treatments: Policy No. 338

Last Approval: 02/12/2025

Next Review Due By: February 2026



DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Plantar Fasciitis (PF) is defined as the inflammation of the plantar fascia, the thick band of connective tissue that connects the heel bone to the base of the toes. Degeneration and inflammation of the plantar fascia caused by repetitive micro trauma leads to chronic heel pain. The characteristic symptom of plantar fasciitis is heel pain, which is usually localized to the plantar medial aspect of the heel. Pain is most noticeable during weight-bearing activities, particularly the first weight-bearing step of the day or following periods of sitting or recumbency. PF is the most common cause of heel pain presenting in the outpatient setting. The exact incidence and prevalence of PF by age are unknown; however, it is estimated that PF accounts for approximately one million patient visits each year (Buchanan & Kushner 2021). A diagnosis of PF is made primarily through the clinical history and physical examination (Schneider et al. 2017).

PF is primarily treated medically, with symptom resolution occurring in up to 95% of patients within 12 to 18 months. 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 are among the first-line standard treatments (Schuitema et al. 2020). If initial treatment fails, second-line options include night splints, steroidal anti-inflammatory injections, or a walking cast. Surgery is reserved for patients who have severe symptoms that have not responded to at least 6-12 months of conservative treatment, but it is also unproven (Buchbinder 2024). This policy addresses minimally invasive therapies that have been studied or used in the treatment of PF in patients without sufficient improvement from initial measures.

RELATED POLICIES / PROCEDURES

MCP 207: Platelet-Rich Plasma (PRP)

MCP 402: Plantar Fasciitis Surgery

COVERAGE POLICY

Minimally invasive therapies for plantar fasciitis are considered **experimental, investigational and unproven** due to insufficient clinical evidence and peer-reviewed medical literature establishing long-term safety, efficacy and effect on net health outcomes. Unproven minimally invasive treatment strategies for plantar fasciitis include, **but are not limited to**, the following:

- Acupuncture
- Amniotic-derived allografts (e.g., human amniotic membrane injections)
- Autologous whole blood or platelet-rich plasma injections
- Botulinum toxin
- Coblation therapy (cold or controlled ablation) (e.g., Topaz MicroDebrider)
- Complementary Therapies (e.g., topical application of various non-FDA approved creams to the foot)

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- Cryosurgery (cryoablation or cryotherapy)
- Extracorporeal Shock Wave Therapy (ESWT)
- Laser therapy or Low-level Laser Therapy (LLLT) (application of LLLT to the heel)
- Radiofrequency Nerve Ablation (RFNA) (Radiofrequency Thermal Ablation or Radiofrequency Lesioning)
- Radiotherapy
- Stem cell therapy
- Trigger point/dry needling

The therapies addressed in greater detail in the 'Summary of Medical Evidence' section are not inclusive of all minimally invasive therapies and only include those with more available data, clinical trials, published peer-reviewed literature, or systematic reviews associated with plantar fasciitis.

SUMMARY OF MEDICAL EVIDENCE

The overall quality of evidence for minimally invasive therapies for plantar fasciitis (PF) is low, primarily due to limitations such as insufficient studies, lack of randomization or blinding, small sample sizes, short-term follow-up, and inconsistent or absent comparators. An updated evidence-based review on PF identifies several minimally invasive treatments—such as autologous whole blood or PRP injections, botulinum toxin injections, cryosurgery, extracorporeal shock wave therapy (ESWT), low- and high-level laser therapy, micronized dehydrated human amnion/chorion membrane injections, and radiotherapy—as unproven (Buchbinder 2024). To better assess the safety, efficacy, and outcomes of these therapies, large randomized controlled trials with long-term follow-up are needed, particularly those comparing minimally invasive options to other medical management strategies. While these emerging treatments may serve as alternatives for patients who do not respond to conservative care, they are not currently recommended for routine use. A summary of relevant studies is provided below.

Amniotic Tissue Derived Allografts or Human Amnion/Chorion Membrane Injections

Amniotic tissue-derived allografts or human amnion/chorion membrane injections (e.g., Amniofix) involve injecting amniotic tissue into the plantar fascia at the site of maximum tenderness caused by chronic PF. Fetal tissue is thought to have unique healing properties absent in adult tissue. These properties may promote the regeneration and epithelialization of damaged tissue while reducing inflammation and scar tissue formation. The tissue is obtained during a selective cesarean section from a healthy pregnancy, then thoroughly cleaned, disinfected, and processed. Preservation methods for amniotic membrane tissues typically include dehydration and cryopreservation to maintain its therapeutic properties.

Randomized Controlled Trials

Cazzell et al. (2018) conducted a prospective, single-blind randomized controlled trial (RCT) to evaluate the safety and effectiveness of micronized, dehydrated human amnion/chorion membrane (dHACM) injections (Amniofix) for treating PF. Patients were randomized to receive a single injection of Amniofix (n = 73) or a sodium chloride placebo (n = 72). The primary outcome measured was the mean change in visual analog scale (VAS) scores from baseline to three months post-injection. Results indicated that a single dHACM injection provided clinically significant improvements in pain and foot function compared to the placebo at three months. However, data on outcomes at six and twelve months were not reported. No serious adverse events related to the study were observed, though some patients experienced post-injection pain and itching after the dHACM injection. The study's limitations include a small sample size and short-term follow-up duration. Additionally, the effectiveness of repeated injections for persistent symptoms remains unclear. Further research, including larger trials with long-term follow-up, is necessary to validate these findings.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

A health technology assessment concluded that the evidence supporting human amniotic membrane injections for reducing pain and improving function in adults with chronic PF is of low quality, with substantial uncertainty regarding their comparative effectiveness and long-term safety beyond 12 weeks post-injection. The low quality of evidence is attributed to several factors, including design limitations of individuals studies, inconsistent outcomes, variability in treatment protocols, a lack of studies with active comparators, and a limited number of available studies. Common limitations among the studies include small sample sizes, absence of active comparators, lack of double blinding, and short follow-up periods. The studies examined several types of human amniotic-derived products and administration procedures, making it unclear whether the methods were comparable. Notably, none of the eligible studies assessed

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the comparative effectiveness of amniotic tissue–derived treatments against other injection therapies, such as platelet-rich plasma or botulinum toxin, or alternative treatments like extracorporeal shock wave therapy (ESWT) or surgery (Hayes 2022).

Autologous Whole Blood (AWB) and Platelet-Rich Plasma (PRP) injections

Autologous whole blood injections have been suggested as a treatment for PF due to their content of growth factors, which may trigger a cascade of local responses to promote angiogenesis and tissue healing (Buchbinder 2024). Platelet-rich plasma (PRP), a specialized autologous blood product with a high concentration of platelets and platelet-derived growth factors is thought to enhance these effects. These growth factors, along with other cytokines, are believed to play a key role in the potential benefits of PRP therapy. By introducing PRP into tissues with limited healing capacity, it is thought to stimulate regeneration and support tissue repair. However, the lack of standardization in PRP preparation for therapeutic usage raises concerns, as it contributes to variability in clinical efficacy and patient outcomes (Fitzpatrick et al. 2017).

Systematic Reviews and Meta-Analyses

Masiello et al. (2023) conducted a systematic review and meta-analysis evaluating ultrasound-guided injections of platelet-rich plasma (PRP) for tendinopathies. The review included 33 studies (2,025 participants), with five of these studies focused on plantar fasciitis. PRP injections were compared to various controls such as ultrasound-guided injections steroid injections, saline, autologous whole blood, local anesthetic, dry needling, prolotherapy, bone marrow mesenchymal stem cells, and non-injection interventions. Primary outcomes included pain measured by visual analog scales and functional outcomes measured using the American Orthopedic Foot and Ankle Society (AOFAS) Score and the Foot Function Index (FFI). Results showed no significant differences in pain between PRP and controls at 1, 3, 6, or 12 months. Functional outcomes were also comparable at 1, 3, and 6 months, with a statistically significant improvement observed in the PRP group at 12 months ($p = 0.04$). However, the quality of evidence was rated as low due to imprecision, inconsistency, and risk of bias across studies. The analysis concluded that there is currently insufficient evidence to support the use of ultrasound-guided PRP injections for the treatment of plantar fasciitis.

Yang et al. (2017) performed a meta-analysis to evaluate the safety and efficacy of PRP as a treatment for PF compared to corticosteroid treatments. The follow-up duration ranged from 16 weeks to one year, with most studies having follow-up periods of six months or less. The analysis included randomized controlled trials or prospective cohort studies that compared PRP to a control group, such as steroid treatment, in patients diagnosed with PF. No significant differences in the VAS scores were observed between the two groups in the short- and intermediate-term. However, PRP demonstrated better long-term efficacy compared to corticosteroid treatments. The meta-analysis was limited by small sample sizes and variability between studies. Additional well-designed, long-term, high-quality RCTs with larger sample sizes are needed to better establish the role of PRP in treating PF.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

A technology assessment evaluated the safety and effectiveness of platelet-rich plasma (PRP) injections compared to corticosteroid injections for treating plantar fasciitis in adults. The review included 7 clinical studies, all of which directly compared PRP to corticosteroid injections. The findings suggest that PRP injections are generally more effective in reducing pain and improving foot and ankle function. Six of the seven randomized controlled trials (RCTs) reported significant pain reduction in favor of PRP, as measured by visual analog scale (VAS) scores in five studies and Foot Function Index (FFI) scores in one study. Similarly, five of six studies assessing foot and ankle function showed significant improvements with PRP, based on FFI disability scores, American Orthopaedic Foot and Ankle Society (AOFAS) scores, and Roles and Maudsley scores. While most studies favored PRP, some results were mixed or comparable. One study found PRP superior to corticosteroids at six months but inferior at three months based on AOFAS scores. Two studies reported no significant differences between the treatments in certain outcomes, and one study found no difference in pain or function improvements. Despite these variations, the overall evidence, though of low quality, indicates that a single PRP injection is safe and may provide greater benefits than corticosteroids or pretreatment levels. However, uncertainties remain regarding the optimal PRP preparation, injection protocols, long-term effectiveness, and comparisons to standard therapies other than corticosteroids (Hayes 2024).

Extracorporeal Shock Wave Therapy (ESWT)

Extracorporeal Shock Wave Therapy is an FDA-approved, non-surgical treatment for chronic heel pain associated with PF. For individuals who have not responded to conventional medical therapies, ESWT offers a noninvasive alternative to surgical intervention. The proposed mechanisms of action include hyperstimulation, analgesia, and the stimulation of neovascularization and collagen synthesis in degenerative tissue (Sun et al. 2017). The goal of ESWT is to alleviate pain and promote healing in the affected soft tissue by delivering shock waves to the heel. These shock

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waves disrupt scar tissue, causing microscopic damage that stimulates the formation of new blood vessels and supports tissue repair. ESWT is available in two forms: low-energy and high-energy, both of which are delivered as outpatient procedures. Low-energy ESWT is typically performed in-office without anesthesia, while high-energy ESWT requires anesthesia and is conducted in a hospital or ambulatory surgery center.

Systematic reviews and meta-analyses have evaluated ESWT, including comparisons with corticosteroid injections, but the results have been inconsistent. The varying results may be attributed to the lack of uniform outcome definitions, variations in ESWT protocols (e.g., number and duration of shocks, frequency of treatments, and differences in focus versus radial, and low- versus high-intensity treatments), and differing comparison subjects. Some studies have reported significant pain relief and functional improvement at three months, but it remains unclear whether ESWT provides lasting benefits beyond this period or alters the long-term course of the disease. According to an evidence-based peer review, while ESWT has been studied more extensively than other treatment modalities of PF, high-quality evidence suggests it is ineffective and is not recommended for routine use (Young & Dijkstra 2024). The available evidence is insufficient to conclude that ESWT improves net health benefits or efficacy outcomes.

Randomized Controlled Trials

Gezginaslan and Başar (2021) conducted a double-blind randomized controlled trial to investigate the impact of ESWT session density and energy levels on pain, fatigue, disability, physical function, and quality of life in patients with plantar fasciitis. Participants were randomly assigned to one of three groups: Group 1 (n = 33) received seven sessions of high-energy flux density ESWT (H-ESWT) at 0.26 mJ/mm², Group 2 (n = 31) received three sessions of H-ESWT at 0.26 mJ/mm², and Group 3 (n = 30) received seven sessions of low-energy flux density ESWT at 0.08 mJ/mm², with treatments spaced three days apart. Outcomes were assessed using the Visual Analog Scale (VAS), Short Form-36 (SF-36), Foot Function Index (FFI), Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue Scale, and the Six-Minute Walking Test (6MWT). Measurements were taken at baseline and one month after treatment. Results showed significant reductions in VAS, FACIT, and FFI scores across all groups post-treatment compared to baseline, indicating decreased pain, fatigue, and disability. Additionally, significant improvements were observed in the 6MWT and SF-36 subscale scores, reflecting enhanced physical function and quality of life. The authors concluded that high-energy ESWT delivered over a higher number of sessions is more effective than low-energy ESWT for improving pain, physical function, fatigue, disability, and quality of life in patients with plantar fasciitis. However, the one-month follow-up period limited the ability to assess intermediate and long-term outcomes. The small sample size (n = 94) also raises questions about the generalizability of the findings.

Systematic Reviews and Meta-Analyses

Al-Siyabi et al. (2022) performed a systematic review and meta-analysis comparing the outcomes of ESWT versus ultrasound therapy (UST) in PF. The review included seven studies with a total of 369 patients comparing the use of ESWT and ultrasound therapy. No significant difference was found between ESWT and UST for functional impairment, American Orthopedic Foot and Ankle Society (AOFAS) scale score, or pain in the first steps in the morning; however, there was a significant improvement in pain during activity for the ESWT group. For secondary outcomes, ESWT had improved results in terms of primary efficacy success rate (the reduction of heel pain), activity limitations, and patient satisfaction. The reduction in plantar fascia thickness showed no significant difference. Pain intensity after treatment had varied results among the included studies. The authors noted that the identification of 7 studies with a sample of 369 patients may not be sufficient to make definitive conclusions and recommended additional clinical trials with larger sample sizes to further evaluate the current findings.

Sun et al. (2017) compared the effectiveness of general ESWT, focused shock wave, and radial shock wave to placebo in a meta-analysis of 9 RCTs and 935 patients with chronic PF. ESWT had better pain outcomes when compared to a placebo (p < 0.00001). Focused shock wave and radial shock wave therapy also showed significant improvements in pain outcomes when compared to placebo (p < 0.001; p = 0.02). Some patients reported discomfort, pain, swelling, and bruising during or after treatment, but there were no reports of serious adverse events. Additional high-quality clinical trials and systematic reviews are needed to demonstrate the efficacy of ESWT.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

A health technology assessment examined the evidence from ten RCTs for the efficacy of radial ESWT for chronic PF. The analysis included a moderate-sized body of low-quality evidence with contradictory findings. Evidence suggests that radial ESWT may reduce patient-reported pain and improve functional outcomes in the short term. Variations in ESWT treatment protocols were used across studies, and many studies did not fully report the treatment parameters used. Methodological flaws in the body of evidence included small sample size, lack of long-term follow-up, high loss to follow-up, and confounding from secondary treatments (Hayes 2022).

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Another health technology assessment reviewed evidence of focused ESWT for chronic PF from 17 RCTs, finding moderate-quality evidence that ESWT may reduce patient-reported pain and improve functional outcomes in the short term; however, the results are contradictory. The evidence suggests that focused ESWT is safe, with only minor side effects. Due to limitations in current published studies, such as conflicting results, a lack of blinding, secondary treatment confounding, and a high loss to follow-up, additional studies with stronger methodologies, such as better controlled, blinded, with long-term follow-up, are required to demonstrate safety and effectiveness (Hayes 2022).

Laser Therapy

Laser therapy, also known as low-level laser therapy (LLLT), is a phototherapy technique that uses low-power, monochromatic, and coherent light to promote healing in injuries and lesions. LLLT may improve the speed, quality, and tensile strength of tissue repair, reduce inflammation, and alleviate pain. High-intensity laser therapy (HILT), which operates at a higher power, is designed to target larger and deeper tissues by utilizing shorter emission times and longer intervals between laser pulses. However, evidence supporting the efficacy of laser therapy for treating plantar fasciitis (PF) is limited. The overall quality of available evidence is very low due to methodological limitations in individual studies and a lack of sufficient research.

Randomized Controlled Trials

Zare Bidoki et al. (2024) conducted a double-blind randomized controlled trial to compare High-intensity Laser Therapy (HILT) and Extracorporeal Shock Wave Therapy (ESWT) in patients with plantar fasciitis (PF). Thirty-eight patients (18-55 years old) who had not responded to conservative treatments after six weeks were included. The study excluded patients with certain medical histories, including recent surgeries, systemic diseases, or contraindications to the treatments. Participants were divided into two groups: ESWT (n=19) and HILT (n=19). The study measured pain, tenderness, and quality of life using the Visual Analogue Score (VAS), Heel Tenderness Index (HTI), and SF36 questionnaire. Both treatments showed significant improvements in pain and patient satisfaction three months post-treatment. Statistically, HILT was more effective than ESWT (P=0.03 for VAS, P=0.006 for HTI, P=0.002 for SF36). There was a significant reduction in pain and tenderness in both groups (P<0.001), and both groups showed significant improvements in quality of life (P<0.001). The study had limitations, including the lack of long-term follow-up and limited treatment sessions due to COVID-19 restrictions. Overall, both therapies were safe, non-invasive, and effective, with HILT being preferred for its higher effectiveness in pain relief and improved quality of life, as well as being more accessible, less painful, and cost-effective.

Cinar et al. (2018) conducted a RCT to compare the efficacy of LLLT and exercise to orthotic support and exercise (standard of care) in the treatment of PF. The patients were randomized into two groups: LLLT (n = 27) and control (n = 22). The LLLT group received a home exercise program with orthotic support along with a gallium-aluminum-arsenide laser with an 850-nm wavelength for 10 sessions, 3 times per week. The control group received a home exercise program with orthotic support. Functional outcomes were measured by the function subscale of the American Orthopedic Foot and Ankle Society Score (AOFAS-F) and a 12-min walking test, including walking speed, cadence, and activity-related pain using the VAS. The scores were recorded at baseline, 3 weeks, and 3 months after the treatment. There was a significant improvement in the AOFAS-F total score at 3 weeks in both groups, and the groups were comparable in walking speed and cadence at all assessment times. Both groups showed a significant reduction in pain over 3 months; however, the LLLT group had lower pain than the control group at 3 months. Study limitations included the lack of standardization of the LLLT dose and the position of the foot during treatment, as well as the lack of a non-treatment group. The authors concluded that combination therapy of LLLT with usual care is more effective for improving functional outcomes and activity-related pain when compared to usual care alone. Additional RCTs with larger patient populations and long-term follow-up are needed to support the outcomes of this study.

Ordahan et al. (2018) compared the efficacy of LLLT and HILT in 70 patients with PF who were randomized into either the LLLT or HILT groups. LLLT and HILT were performed three times per week over a period of three weeks. Each treatment was combined with silicone insoles and stretching exercises. Patients' pain and functional status were evaluated with the VAS, Heel Tenderness Index, and Foot and Ankle Outcome Score before and after treatment. At the study onset, there were no statistically significant differences between the two groups in the VAS, Heel Tenderness Index, and Foot and Ankle Outcome Scores. Three weeks later, both groups showed significant improvement in all parameters. The HILT group demonstrated better improvement in all parameters than the LLLT group. Although both treatments improved the pain levels, function, and quality of life in patients with PF, HILT had a more significant effect than LLLT. Limitations of this study include lack of blinding to treatment, a small sample size, and a follow-up of only 3 months.

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Systematic Reviews and Meta-Analyses

Wang et al. (2019) conducted a systematic review and meta-analysis to assess whether LLLT significantly relieved the pain of patients with PF. A total of 6 RCTs were included. Compared with the control group, the VAS score significantly decreased at the endpoint of the treatment in the LLLT group. No significant difference was observed according to the Foot Function Index-Pain subscale. The authors concluded that the findings of this meta-analysis showed that LLLT significantly relieved heel pain in patients with PF, and efficacy lasted for 3 months after treatment. Limitations include the small number of studies, insufficient power to analyze other factors that may influence the effect of LLLT treatment, and a lack of longer-term follow-up. Furthermore, the outcome was based solely on VAS, and other objective indices (such as heel tenderness index and PF thickness) were not used in all studies. The authors concluded that LLLT may effectively relieve short-term (e.g., 3 months) heel pain in patients with PF; however, more large-scale, well-designed studies are needed to further clarify the long-term efficacy and optimal treatment parameters of LLLT.

Radiofrequency Nerve Ablation (RFNA), Radiofrequency Lesioning, Radiofrequency Thermal Ablation

Radiofrequency nerve ablation is a technique designed to disrupt pain pathways and is typically used for managing chronic pain that has not responded to conservative treatments. However, it is not a well-established option for treatment PF. A health technology assessment determined that the body of evidence assessing RFNA for the treatment of PF is generally of low quality (Hayes 2020). The included studies were rated as fair to poor due to small sample sizes, lack of comparison groups, and other methodological limitations. The assessment highlighted significant uncertainties regarding the procedure's long-term effectiveness, appropriate patient selection, safety, and comparative efficacy against other minimally invasive treatments.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Erden et al. (2021) conducted a retrospective, comparative study to assess the efficacy of corticosteroid injection (CSI), extracorporeal shock wave therapy (ESWT), and radiofrequency thermal lesioning (RTL) treatments in chronic plantar heel pain that had not responded to other conservative treatments. The outcomes of 217 patients who received CSI (n = 73), ESWT (n = 75), and RTL (n = 69) were assessed. The treatment effectiveness and pain intensity, as measured by the VAS was recorded and compared at the 6-month follow-up. Pain intensity decreased significantly in all patients; however, it decreased significantly more in the CSI and RTL groups than in the ESWT group. There were no complications as a result of the CSI, ESWT, or RTL sessions. The authors concluded that CSI, ESWT, and RTL successfully treated chronic plantar heel pain that had not responded to other conservative treatments; however, CSI and RTL produced better therapeutic outcomes.

Osman et al. (2016) conducted a small, comparative trial (n=20) evaluating the effect of applying pulsed radiofrequency (PRF) for 6 minutes versus thermal radiofrequency (TRF) for 90 seconds to the medial calcaneal nerve for treatment of chronic refractory PF pain. Twenty patients with refractory chronic bilateral PF received PRF to the medial calcaneal nerve for 6 minutes for one heel and TRF to the same nerve on the other heel (as their own control) for 90 seconds. All studied patients showed significant improvement in their pain scale after the intervention that lasted for 24 weeks; however, the PRF heels had significantly better pain scale and satisfaction scores at the first- and third-week assessments when compared to the TRF heels. The authors concluded that PRF to the medial calcaneal nerve is a safe and effective method for treatment of chronic PF pain and the onset of effective analgesia can be achieved more rapidly with PRF compared to TRF. Limitations of this study include lack of randomization, small sample size, and no long-term follow-up. Further randomized trials are needed to confirm the therapeutic effect and optimize the dose of RF needed.

Stem Cell Therapy

Stem cell therapy involves the use of mesenchymal stem cells (MSCs), which can be harvested from sources such as bone marrow, adipose tissue, amniotic membrane, peripheral blood, and synovial tissue. In orthopedics, MSCs are primarily derived from bone marrow. These adult-derived, undifferentiated, and multipotent cells express various cell surface proteins and have the capacity to differentiate into multiple lineages, including adipogenic, osteogenic, and chondrogenic (Young & Dijkstra 2024). Currently, the only FDA-approved stem cell-based products in the United States are for hematopoietic progenitor cells derived from cord blood, which are approved for limited use in treating hematopoietic system disorders. The FDA has raised safety concerns regarding the use of unproven stem cell therapies, including risks such as administration site reactions, failure of cells to function as intended, tumor formation, migration of cells from implantation sites, transformation into inappropriate cell types, and uncontrolled proliferation (FDA 2021). There is a lack of clinical studies demonstrating the efficacy and safety of MSCs in treating PF, and its clinical value in the treatment of PF has not been established.

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Other Treatments

The overall evidence supporting alternative treatments for pain relief associated with plantar fasciitis (i.e., cryosurgery, botulinum toxin injections, radiation therapy, complementary therapies, electric dry needling) is of low quality. This is primarily due to small sample sizes, absence of comparison groups, short follow-up durations, and other methodological flaws. Further well-designed research is necessary to establish the effectiveness and safety of these emerging therapies before they can be recommended for standard clinical practice (Buchbinder 2024).

National and Specialty Organizations

The **American College of Foot and Ankle Surgeons (ACFAS)** issued a consensus statement for diagnosing and treating adult-acquired infracalcaneal heel pain. According to the guidance, "Extracorporeal shockwave therapy (ESWT) is safe and effective in the treatment of plantar fasciitis". Studies consistently show that approximately 70% of patients with chronic or subacute plantar fasciitis experienced significant pain relief 12 weeks after undergoing ESWT. However, ESWT does not appear to be effective as a first-line treatment for acute plantar fasciitis. It is important to note that the consensus does not address conflicting findings or potential biases in studies, such as variations in treatment parameters (e.g., session frequency, number of shocks, device type), blinding versus non-blinding, or subjective versus self-reported data (Schneider et al. 2017).

The **ACFAS** panel also released consensus statements regarding other injection and surgical techniques (Schneider et al. 2017):

- The safety and effectiveness of emerging injection therapies (e.g., amniotic tissue, platelet-rich plasma, botulinum toxin, needling, and prolotherapy) in the treatment of plantar fasciitis were deemed uncertain—neither appropriate nor inappropriate. The panel highlighted that these techniques are supported only by low-quality studies, including case series, retrospective comparative studies, or small trials lacking long-term follow-up data. The panel emphasized the need for further research to determine how these therapies compare to conventional treatment protocols.
- The safety and effectiveness of "other surgical techniques (e.g., ultrasonic debridement with a microtip device, cryosurgery, and bipolar radiofrequency ablation) for chronic, refractory plantar fasciitis was uncertain—neither appropriate nor inappropriate." These interventions lack robust long-term data or peer-reviewed studies, and additional research is necessary to evaluate their clinical utility for chronic, refractory plantar fasciitis.

The **American College of Occupational and Environmental Medicine (ACOEM)** also addressed ESWT in its updated 2018 guidelines, stating that it may be used in select patients with chronic, recalcitrant plantar fasciitis (ACOEM 2018).

The **International Society of Stem Cell Research (ISSCR)** provides comprehensive information about stem cell types and applications on its website, emphasizing that "currently, very few stem cell treatments have been proven safe and effective." According to the ISSCR, the range of diseases for which stem cell therapies have demonstrated benefits remains limited. The most well-established and extensively utilized stem cell treatment is hematopoietic stem cell transplantation. Additionally, certain bone, skin, and corneal injuries or diseases can be treated through tissue grafting or implantation, with the healing process relying on stem cells present in the implanted tissue. These procedures are widely recognized by the medical community as both safe and effective. However, the ISSCR cautions that all other applications of stem cells remain unproven in clinical trials and should be regarded as highly experimental (ISSCR, date unknown).

The **National Institute for Health and Clinical Excellence (NICE)** released interventional procedure guidance on autologous blood injections for plantar fasciitis (PF), stating that while there are no significant safety concerns, the available evidence regarding efficacy is insufficient in both quantity and quality. As a result, this procedure should only be performed under special arrangements, including clinical governance, consent, and audit or research protocols. NICE recommends further studies to compare autologous blood injections (with or without platelet-rich plasma techniques) to established treatments for PF. These trials should clearly define patient selection criteria, such as symptom duration and previous treatments, and use specific measures of pain and function as outcomes (NICE 2013).

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CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed
0552T	Low-level laser therapy, dynamic photonic and dynamic thermokinetic energies, provided by a physician or other qualified health care professional
20550	Injection(s); single tendon sheath, or ligament, aponeurosis (e.g., plantar "fascia")
20552	Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)
20553	Injection(s); single or multiple trigger point(s), 3 or more muscles
20560	Needle insertion(s) without injection(s); 1 or 2 muscle(s)
20561	Needle insertion(s) without injection(s); 3 or more muscles
20999	Unlisted procedure, musculoskeletal system, general
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
64640	Destruction by neurolytic agent; other peripheral nerve or branch
64642	Chemodenervation of one extremity; 1-4 muscle(s)
64643	Chemodenervation of one extremity; each additional extremity, 1-4 muscle(s) (List separately in addition to code for primary procedure)
64644	Chemodenervation of one extremity; 5 or more muscles
64645	Chemodenervation of one extremity; each additional extremity, 5 or more muscles (List separately in addition to code for primary procedure)
77401	Radiation treatment delivery, superficial and/or ortho voltage, per day
77499	Unlisted procedure, therapeutic radiology treatment management
97024	Application of a modality to 1 or more areas; diathermy (e.g., microwave)
97810	Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
97811	Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)
97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
97814	Acupuncture, 1 or more needles; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
J0585	Injection, onabotulinumtoxinA, 1 unit
J0586	Injection, abobotulinumtoxinA, 5 units
J0587	Injection, rimabotulinumtoxinB, 100 units
J0588	Injection, incobotulinumtoxinA, 1 unit
J0589	Injection, daxibotulinumtoxina-lanm, 1 unit
Q4100	Skin substitute, not otherwise specified
Q4139	AmnioMatrix or BioDMatrix, injectable, 1 cc
Q4174	PalinGen or ProMatrX, 0.36 mg per 0.25 cc
Q4192	Restorigin, 1 cc
Q4215	Axolotl Ambient or Axolotl Cryo, 0.1 mg
S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low-level

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laser; each 15 minutes

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

- 02/12/2025** Policy reviewed. No changes in coverage criteria. Updated summary of medical evidence and references. IRO Peer Review on January 21, 2025, by a practicing physician board-certified in Orthopedic Surgery.
- 02/14/2024** Policy reviewed and updated. No changes in coverage criteria. Updated summary of medical evidence and references.
- 02/08/2023** Policy reviewed and updated. No changes in coverage criteria. Updated references.
- 02/09/2022** Policy reviewed and updated. IRO Peer Review. Reviewed by practicing physician board-certified in Orthopedic Surgery. Updated summary of medical evidence and references. Added CPT codes 0481T, 64642, 64643, 64644, 64645. Added extracorporeal shock wave therapy, acupuncture, coblation therapy, stem cell therapy, and trigger point dry needling to coverage section.
- 02/08/2021** Policy reviewed. No changes in coverage criteria. Updated summary of medical evidence and references.
- 04/23/2020** Policy reviewed. No changes in coverage criteria.
- 03/11/2019** New policy. IRO Peer Review 2/1/2019. Reviewed by practicing physician board-certified in Orthopedic Surgery.

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