Molina Clinical Policy
Plantar Fasciitis Treatments: Policy No. 338

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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 inflammation of the plantar fascia, the thick fibrous band of connective tissue that supports the arch of the foot and is situated between the heel bone and the base of the toes. The specific etiology of PF is unknown and may be multifactorial, but repetitive microtrauma is suspected of causing plantar fascia degeneration and inflammation, resulting in heel pain characterized by severe pain in the inferior or plantar aspect of the center or medial 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 1 million patient visits each year (Buchanan; Kushner, 2021). A diagnosis of PF is made primarily through the clinical history and physical examination (ACFAS 2017). Imaging studies are generally not necessary for diagnosis but may be useful in identifying other plausible etiologies if appropriate initial therapy fails or if the clinical presentation is atypical. 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 for PF (Schuitema et al., 2020). If early treatment fails, second-line options include night splints, steroidal anti-inflammatory injections, or a walking cast. Surgery is generally 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, 2021). 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

Platelet-Rich Plasma (PRP): Policy No. 207
Plantar Fasciitis Release Surgery: Policy No. 402

COVERAGE POLICY

Minimally invasive therapies for PF 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 PF 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)

- 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 relatively more available data, clinical trials, published peer-reviewed literature, or systematic reviews associated with PF.

SUMMARY OF MEDICAL EVIDENCE

Overall, the quality of evidence for minimally invasive therapy for PF (i.e., autologous whole blood, platelet-rich plasma, Botulinum toxin, cryosurgery, laser therapy, other complementary therapies, radiofrequency, and radiotherapy techniques) is low due to insufficient studies with design limitations, lack of randomization and/or blinding, small sample size, generally short-term follow-up, and lack of and inconsistent comparators. An updated evidence-based peer review on "Plantar fasciitis" (Buchbinder, 2022) lists autologous whole blood or PRP injections, botulinum toxin injection, cryosurgery, ESWT (low- and high-level laser therapy), micronized dehydrated human amnion/chorion membrane injection, and radiotherapy as unproven treatments. Large randomized controlled trials (RCTs) comparing minimally invasive therapy for PF with other medical management strategies over a long duration of follow-up are required to evaluate outcomes, safety and efficacy. A summary of relevant and valid studies is provided below. Minimally invasive therapies for PF are emerging therapies that provide an alternative after conservative therapies fail; however, these modalities are not currently recommended in routine care.

Amniotic Tissue Derived Allografts or Human Amnion/Chorion Membrane Injections

Amniotic tissue-derived allografts or human amnion/chorion membrane injections (e.g., Amniofix) involve injection of amniotic tissue into the plantar fascia, where chronic PF has the maximum tenderness. Fetal tissue is theorized to have healing properties not found in normal adult tissues, which can promote the epithelialization and regeneration of damaged tissues and limit the formation of inflammation and scar tissue. During a selective cesarean section for a healthy pregnancy, amniotic membrane tissue can be obtained and then cleaned, disinfected, and processed. The process of preserving human amniotic membrane tissue includes dehydration and cryopreservation. Several allographs derived from human amniotic tissues are available.

A prospective, single-blind RCT (n = 145) investigated the safety and effectiveness of a micronized, dehydrated human amnion/chorion membrane (dHACM) injection (Amniofix) for the treatment of PF (Cazzell et al., 2018). Patients were randomized to receive one injection of Amniofix (n = 73) or a 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. The study reported that a single dHACM injection resulted in clinically relevant benefits in pain and foot function at 3 months compared with a placebo. However, the collected outcomes at 6 and 12 months were not reported. No serious adverse events were related to the study, but there were 3 adverse events following the dHACM injection (2 patients with post-injection pain and 1 with itching). 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. Further trials are needed to confirm these results.

A health technology assessment (2022) concluded that there is a low-quality body of evidence indicating human amniotic membrane (HAM) injections reduce pain and improve function in adults with chronic PF and substantial uncertainty remains regarding the comparative effectiveness and the long-term efficacy and safety beyond 12 weeks post-injection. The body of evidence evaluating injectable amniotic tissue-derived allografts for the treatment of PF was of low quality, consisting of two fair-quality RCTs, one poor-quality RCT, and one very-poor-quality pretest/posttest study (n = 23-147) (Zelen et al., 2013; Hanselman et al., 2015; Werber, 2015; Cazzell et al., 2018). This quality rating is primarily due to individual study quality, inconsistency in outcomes, variability of treatment protocols across studies, a lack of studies evaluating active comparators, and a limited amount of evidence. Limitations of the individual studies include small sample sizes, a lack of an active comparator (3 studies), a lack of

double-blinding (3 studies), and limited follow-up (12 weeks or less). The studies also used different types of human amniotic–derived products and administration procedures, and it is unclear whether these products and administration approaches were comparable across studies. None of the eligible studies examined the comparative effectiveness of amniotic tissue–derived treatments compared with other types of injections (platelet-rich plasma, botulinum toxin), ESWT, or surgery (Hayes, 2022).

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

AWB injections have been proposed as a treatment for PF on the basis that they contain various growth factors that may initiate a cascade of local factors to stimulate angiogenesis and healing (Buchbinder, 2022). PRP is an autologous blood preparation with a high platelet concentration and concentrated platelet-derived growth factors and other cytokines, which may be the primary contributors to the benefits of PRP therapy. It is proposed that introducing PRP into tissues with low healing potential may stimulate regeneration and promote tissue repair. The lack of standardization of PRP preparation for therapeutic usage is concerning considering its variable clinical efficacy and clinical outcomes (Hashimoto et al., 2016; Fitzpatrick et al., 2017).

A health technology assessment addressing the PRP for treatment of conditions of the Achilles Tendon and Plantar Fascia concluded that a small body of low-quality evidence suggesting that functional improvement and pain relief may be superior with PRP injections compared with corticosteroid injections in PF patients. Additionally, the report notes that there is limited, low-quality evidence suggesting that functional improvement and pain relief may not differ between PRP and saline, extracorporeal shockwave therapy, endoscopic plantar fasciotomy, or low dose radiation in PF patients (Hayes, 2022). The review included eight studies on the use of PRP in the treatment of PF. Several comparator studies were conducted, including corticosteroid (CS) (Monto, 2014; Jain et al., 2015; Acosta-Olivo et al., 2016; Vahdatpour et al., 2016a), ESWT and conventional treatment (Chew et al., 2013), endoscopic plantar fasciotomy (EPF) (Othman and Hegazy, 2015), and low dose radiation (LDR). Three studies found that PRP was more effective than CS in terms of function and pain outcomes, while one study found no difference. The study that found no difference on these measures may have been too brief, with only 16 weeks of follow-up for PRP benefits to be evident. The remaining studies found no correlations between PRP and ESWT, EPF, or LDR. There was also some limited evidence that suggested PRP may produce better functional outcomes than traditional physical therapy. PRP does not appear to provide better functional and pain outcomes than comparator treatments (Hayes, 2022).

Yang et al. (2017) performed a meta-analysis (n = 9 RCTs; 430 patients) to evaluate the current evidence on the safety and efficacy of PRP as a treatment for PF compared to corticosteroid treatments. The length of follow-up ranged from 16 weeks to 1 year, and most were 6 months or less. RCTs or prospective cohort studies that compared PRP to a control (e.g., steroid treatment) in patients diagnosed with PF were included. 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 than steroid treatments. The authors concluded that limited evidence supported the conclusion that PRP is superior to corticosteroid treatments for long-term pain relief; however, significant differences were not observed between short and intermediate effects. Limitations of this meta-analysis include the small sample size and heterogeneity between studies. Additional well-designed, long-term, and high-quality RCTs with larger sample sizes are needed to establish the role of PRP as a treatment for PF.

Extracorporeal Shock Wave therapy (ESWT)

ESWT is an FDA-approved non-surgical treatment option for chronic PF heel pain. For selected individuals who have failed conventional medical therapy, ESWT may be a noninvasive alternative to surgical treatment. Hyperstimulation, analgesia, and stimulation of neovascularization and collagen synthesis in degenerative tissues are among the hypothesized processes behind the effects of ESWT (Sun et al. 2017; Speed 2014). The goal of ESWT is to reduce pain and promote healing of the affected soft tissue by delivering shock waves to the heel. Theoretically, shock waves relieve pain by disrupting scar tissue and causing microscopic damage to that tissue. This promotes the formation of new blood vessels in the injured area, facilitating the healing process. This treatment is available in two variations: low-energy and high-energy, both of which are delivered as outpatient services. High-energy ESWT is performed in a hospital or ambulatory surgery center under anesthesia. In the office, low-energy ESWT is typically used without anesthesia.

Several systematic reviews and meta-analyses have been conducted, including studies comparing ESWT with corticosteroid injections; however, the summary results are inconsistent. Some meta-analyses reported pain reduction, while others reported that the pain reduction was not significant. The varying results may be attributed to

the lack of uniformity in the definition of results, the variability of ESWT treatment regimens (i.e., the number and duration of shocks per treatment, the number of treatments, the different subjects of comparison, and the focus vs. radial, low intensity vs. high intensity and vitality). Some studies have reported significant benefits in terms of pain relief and functional improvement at 3 months, but it is not evident whether ESWT improves pain and function beyond the 3 months or whether it alters course of the disease in the long-term. According to an evidence-based peer review, while ESWT has been studied more extensively than any other single treatment modality for PF, there is high-quality evidence that it is ineffective in treating PF and is therefore not recommended for routine use (UpToDate, 2021). The available evidence is insufficient to conclude that ESWT improves net health benefits and efficacy outcomes.

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.

Gezginaslan and Başar (2021) conducted a double-blind, randomized controlled trial (RCT) to investigate the effect of density and number of sessions ESWT on pain, fatigue, disability, physical function, and quality of life in patients with PF (n = 94). All patients were divided into three groups at random. Group 1 (n = 33) received 7 sessions of high-energy flux density (H-ESWT) (0.26 mJ/mm2), Group 2 (n = 31) received 3 sessions of H-ESWT (0.26 mJ/mm2), and Group 3 (n = 30) received 7 sessions of low-energy flux density (0.08 mJ/mm2) with a 3-day interval. The 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 between groups at baseline and 1 month after treatment. However, the VAS, FACIT, and FFI scores were statistically lower in all groups after treatment compared to baseline, with only the 6MWT and Short Form-36 subscale scores statistically higher. The authors concluded that H-ESWT for a high number of sessions is more effective than LESWT for a low number of sessions in patients with PF in terms of pain, quality of life, physical function, fatigue, and disability. The one-month follow-up period did not allow for the evaluation of intermediate and long-term outcomes. Because of the small sample size (n = 94), it is difficult to determine whether these findings can be generalized to a larger population. More research is required before the procedure's clinical utility can be determined.

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. There were no reports of serious adverse events. ESWT had better pain outcomes when compared to a placebo. Focused shock and radial shock also showed significant improvements in pain outcomes when compared to placebo. Limitations of the analysis include the lack of comparison to established treatment methods. Additional high-quality clinical trials and systemic reviews are needed to demonstrate the efficacy of ESWT.

A health technology assessment examined the evidence from ten RCTs for the efficacy of radial ESWT for chronic PF (Hayes 2022). The analysis included a moderate-sized body of low-quality evidence with contradictory findings. Some evidence suggests that radial ESWT may reduce patient-reported pain and improve functional outcomes in the short term. Several 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.

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 relatively 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.

The American College of Foot and Ankle Surgeons (ACFAS) issued a consensus statement in 2017 for the diagnosis and treatment of adult acquired infracalcaneal heel pain. "Extracorporeal shockwave therapy (ESWT) is safe and effective in the treatment of plantar fasciitis," according to the guidance. A common finding across all studies was that approximately 70% of patients with chronic or subacute PF who underwent ESWT experienced meaningful improvement in their heel pain at 12 weeks. However, ESWT does not appear to be an effective first-line treatment option for patients with acute PF. It should be noted that the consensus does not address the conflicting findings or potential bias and variations from the low-quality studies such as the inconsistent treatment parameters across study protocols (i.e., the number of sessions and shocks, type of device, blinding vs. non-blinding, type of data reported: subjective, self-reported).

The American College of Occupational and Environmental Medicine (ACOEM) updated 2018 guidelines state that ESWT for chronic plantar fasciitis may be used in select patients with chronic recalcitrant conditions (insufficient evidence, consensus-based (ACOEM, 2018).

Laser Therapy

Laser therapy, also known as low-level laser therapy (LLLT), is a form of phototherapy that involves the application of low-power monochromatic and coherent light to injuries and lesions to stimulate healing. In theory, LLLT can improve the speed, quality, and tensile strength of tissue repair, resolve inflammation, and relieve pain. High-intensity laser therapy (HILT) can stimulate larger and deeper targets due to its higher power than low-level lasers with a shorter laser emission time and a longer laser emission interval. The available data regarding the efficacy of laser therapy for the treatment of PF is limited. There is an overall very low-quality body of evidence for laser therapy as a treatment for relief of pain due to individual study limitations and a limited quantity of evidence.

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.

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 P. 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.

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 LlIT 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. There are several limitations to this systematic review and meta-analysis, including the small number of studies (six), insufficient power to analyze other factors (e.g., BMI) 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 included. 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 (RFL), Radiofrequency Thermal Ablation,

RFNA is a technique for ablating pain pathways that is commonly used for intractable pain that has not responded to conservative measures. Radiofrequency lesioning is not a well-established treatment for PF. A health technology assessment determined that the body of evidence assessing RFNA for the treatment of PF is in general of very low quality (Hayes, 2021). The studies included in the evidence base were rated ranged in quality from fair to very poor quality due to small sample sizes, a lack of comparison groups, and other methodological flaws. It was concluded that significant uncertainty exists regarding the durability, patient selection, safety, and the comparative efficacy of RFNA versus other minimally invasive treatments (Liden et al., 2009; Landsman et al., 2013; Erken et al., 2014; Counsel et al., 2016; Osman et al., 2016).

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; very 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.

Erden et al. (2021) conducted a retrospective, comparative study to assess the efficacy of corticosteroid injection (CSI), 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, were 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.

Stem Cell Therapy

Stem cell therapy refers to mesenchymal stem cells (MSC) harvested from bone marrow, adipose tissue, amniotic membrane, peripheral blood and/or synovial tissue. MSCs are derived primarily from bone marrow in orthopedics. 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, osteogenic, and chondrogenic. (Cook, Young, 2019). The only FDA-approved stem cell-based products for use in the United States are hematopoietic progenitor cells derived from cord blood, which are approved for limited use in patients with hematopoietic system disorders (FDA 2019). Safety concerns of the FDA regarding the use of unproven stem cells include administration site reactions, failure of cells to function as predicted, tumor formation, and the ability of cells to migrate from implantation sites, transform into inappropriate cell types, and proliferate (FDA, 2020). Evidence of efficacy and safety from methodologically rigorous clinical studies appears to be lacking, and its clinical value in the treatment of PF has not been established. MSCs remain an experimental therapy for musculoskeletal tissues (e.g., muscle, tendon, and fibrous tissue).

The International Society of Stem Cell Research (ISSCR) provides information on stem cell types and uses on their site, asserting that 'currently there is very few stem cell treatments that have been proven safe and effective.' According to the ISSCR, '*The list of diseases for which stem cell treatments have been shown to be beneficial is still very short. The best-defined and most extensively used stem cell treatment is hematopoietic stem cell transplantation…. Some bone, skin and corneal injuries and diseases can be treated by grafting or implanting tissues,*

and the healing process relies on stem cells within this implanted tissue. These procedures are widely accepted as safe and effective by the medical community. All other applications of stem cells are yet to be proven in clinical trials and should be considered highly experimental' (ISSCR 2023).

Other Treatments

There is an overall low-quality body of evidence for other treatments (i.e., cryosurgery, Botulinum toxin injections, radiation therapy, complementary therapies, electric dry needling) for the relief of pain associated with PF due to individual study limitations and limited quantity of evidence. Studies were of poor quality, small sample sizes, lack of comparison groups, short-term follow-up, and other methodological flaws. Further trials are required before considering these alternative emerging therapies in routine care (Buchbinder, 2022).

National and Specialty Organizations

The **American College of Foot and Ankle Surgeons (ACFAS) (2017)** panel issued consensus statements on injection techniques (e.g., amniotic tissue, platelet-rich plasma, botulinum toxin, needling, and prolotherapy) and other surgical techniques (e.g., ultrasonic debridement using a microtip device, cryosurgery, and bipolar radiofrequency ablation) indicating that these procedures were uncertain, neither appropriate nor inappropriate:

- The safety and effectiveness of "Other injection techniques (e.g., amniotic tissue, platelet-rich plasma, botulinum toxin, needling, and prolotherapy) in the treatment of plantar fasciitis was uncertain— neither appropriate nor inappropriate: (Schneider, et al., 2018), The panel acknowledged that 'Although other injection techniques are emerging for the treatment of plantar fasciitis, they have been supported only by low-quality studies consisting of case series, retrospective comparative studies, or small trials, lacking long-term follow-up data. Rather than speculate on the value of these injection therapies, the panel thought that further investigation is needed to assess how these will compare with the more 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." The panel acknowledged that these treatment options have very little long-term data or peer-reviewed studies. Further research is needed to determine their effectiveness.

The **American Orthopedic Foot & Ankle Society (AOFAS)** updated guidelines (2021) did not address minimally invasive treatment strategies or ESWT. The AOFAS noted the following regarding PF 'With six months of consistent, non-operative treatment, plantar fasciitis will resolve up to 97% of the time. Surgery has the possibility of post-operative complications with continued pain' (AOFAS, 2021).

The **National Institute for Health and Clinical Excellence (NICE)** (2013) issued an interventional procedure guidance stating that the evidence on autologous blood injection for PF raises no major safety concerns. However, the evidence on efficacy is inadequate in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. NICE encourages further research comparing autologous blood injection (with or without techniques to produce PRP) against established treatments for managing PF. Trials should clearly describe patient selection, including duration of symptoms and any prior treatments. Outcomes should include specific measures of pain and function. (No updates since 2013).

SUPPLEMENTAL INFORMATION

Visual Analog Scale (VAS): The intensity of pain in patients with OA assessed by using a visual analogue scale, consisting of a 10 cm-long horizontal line marked with "no pain" on one end, and "worst pain imaginable" on the other end. The patients marked the place that corresponds best to their pain intensity on the given line. The numerical values on the VAS were obtained as the distance in centimeter from "no pain" to the point marked on the line by each patient.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
0232T	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed
0441T	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve
0481T	Injection(s), autologous white blood cell concentrate (autologous protein solution), any site, including image guidance, harvesting and preparation, when performed
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
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)
77499	Unlisted procedure, therapeutic radiology treatment management

HCPCS Codes – N/A

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APPROVAL HISTORY

2/8/2023 Policy reviewed and updated. Revised verbiage and wording for clarity with no changes in intent. Updated references.

2/9/2022 Policy reviewed and updated. No changes in coverage criteria. Updated references. Template updated. Coding reviewed on 6/8/2021; added CPT codes 0481T, 64642, 64643, 64644, 64645. Content updates and revisions include:

- Previous version stated: 'Plantar Fascia release surgery and Extracorporeal Shock Wave Therapy (ESWT) are recommended when all other medical management has failed.' Added ESWT to the 'Coverage Policy' section as 'experimental, investigational and unproven'
- Added the following procedures to the 'Coverage Policy' section:
  - Acupuncture
  - Coblation therapy (cold or controlled ablation, e.g., Topaz MicroDebrider)
  - Extracorporeal Shock Wave Therapy (ESWT)
  - Stem cell therapy
  - Trigger point dry needling
- Addressed the following procedures in the 'Summary of Evidence' section: Amniotic tissue derived allografts or human amnion/chorion membrane injections, ESWT, Stem Cell Therapy

2/8/2021 Policy reviewed. Added one additional Hayes report under reference (Human Amniotic Membrane Injections) considered I/E.

4/23/2020 Policy reviewed, no changes.

3/11/2019 New policy. IRO Peer Review 2/1/2019. Reviewed by practicing physician board-certified in Orthopedic Surgery.

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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*