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 lies between the heel bone and the base of the toes and supports the arch of the foot. The exact etiology of PF is unclear and may be multifactorial, although repetitive microtrauma is suspected of causing the degeneration and inflammation of the plantar fascia which results in heel pain. Pain is typically worse in the morning or after a rest period but improves with movement. 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 approximately 1 million patient visits per year are due to PF (Buchanan; Kushner 2021). A diagnosis of PF is made primarily through 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 initial appropriate therapy fails or if the clinical presentation is atypical. PF is primarily treated medically, and up to 95% of patients have symptom resolution within 12 to 18 months. The first-line standard treatments of PF include 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 (Schuitema et al., 2020). Second-line measures if early treatment fails include night splints, steroidal anti-inflammatory injections or a walking cast. Surgery is generally reserved for patients with severe symptoms refractory to at least 6-12 months of conservative treatment, however 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.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Overall, the quality of the evidence is low for minimally invasive therapy for PF (i.e., injections of autologous whole blood, platelet-rich plasma, Botulinum toxin, cryosurgery, laser therapy, other complimentary therapies, radiofrequency and radiotherapy techniques), 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. Large randomized controlled trials (RCTs) comparing minimally invasive therapy for PF with other medical management strategies, over a long period of follow-up are needed to evaluate their indications, outcomes safety and efficacy. A summary of the most relevant and valid studies is provided below. The minimally invasive therapies for PF are emerging therapies and offer an alternative after failure of conservative therapies, 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 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. A number of 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 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 placebo. However, 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 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 Hayes Technology Assessment (HTA) (2019) reviewed the available evidence on the use of human amniotic membrane (HAM) injections for the treatment of chronic PF (n=23 to 147 patients) (Zelen et al., 2013; Hanselman et al., 2015; Werber, 2015; Cazzell et al., 2018). Three of the studies were RCTs that compared allograft treatment with saline-placebo control (2 studies) or corticosteroid injection (1 study). An additional prospective, open-label pre-test/post-test study compared baseline pain assessments with follow-up assessments (Werber, 2015). All studies followed patients for 8 to 12 weeks. Limitations of the individual studies include small sample sizes, lack of an active comparator (3 studies), 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. The HTA also noted that 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. The HTA concluded there is a low-quality body of evidence suggesting HAM injections reduce pain and improve function in adults with chronic PF. However, substantial uncertainty remains regarding the comparative effectiveness and the long-term efficacy and safety beyond 12 weeks post-injection. The quality of evidence is overall low due to individual study limitations, inconsistency in the outcomes across studies, lack of studies evaluating active comparators, and the limited quantity of evidence.

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

AWB injections have been proposed as a treatment for PF on the basis that it contains various growth factors that may begin a cascade of local factors to stimulate angiogenesis and healing (Buchbinder 2021). 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 to tissues with low healing potential may stimulate regeneration and promote tissue repair. The lack of standardization of PRP preparation for clinical use is a concern in its varying clinical efficacy and clinical outcomes (Hashimoto et al., 2016; Fitzpatrick et al., 2017).

Hayes published a comparative effectiveness review on PRP for the treatment of Achilles tendon rupture (ATR) and PF (Hayes 2019; reviewed 2021). The review included 8 studies for the use of PRP in the treatment of PF. Several comparators were examined among the studies, 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) (Gogna et al., 2016). Three studies provided evidence of greater benefit with PRP in both function and pain outcomes compared to CS and 1 study found no difference in these results between PRP and CS. The study that reported no difference on these measures may have been too short, with only 16 weeks of follow-up for PRP benefits to be evident (Acosta-Olivo et al., 2016). The remaining studies failed to detect differences between PRP and ESWT, EPF, or LDR. There was also some limited evidence suggesting functional outcomes may be better with PRP than with conventional physical therapy (Chew et al., 2013). The comparative review noted that PRP does not appear to lead to superior functional and pain outcomes than comparator treatments.

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. 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-term 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 persistent heel pain associated with chronic PF. ESWT purportedly may be a noninvasive alternative to surgical treatment in selected individuals who have failed conventional medical therapy. The proposed mechanisms for the effect of ESWT include hyperstimulation analgesia and stimulation of neovascularization and collagen synthesis in degenerative tissues (Sun et al. 2017; Speed 2014). ESWT delivers shock waves to the heel with the goal of reducing pain and promoting healing of the affected soft tissue. Shock waves are theorized to relieve pain by disrupting scar tissue and causing microscopic damage to that tissue. This induces new blood vessel formation into the injured area and facilitates the healing process. There are two forms of this treatment, low-energy and high-energy performed on an outpatient basis. High-energy ESWT requires the use of anesthesia and is performed in a hospital or ambulatory surgery center. Low-energy ESWT is usually used in the office 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 /vitality). Some studies have reported significant benefits of pain 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. An UpToDate review (2021) indicates that while ESWT is noted as more extensively studied than any other single treatment modality for PF, there is high-quality evidence that it is ineffective in treating PF and is not recommended for routine use (Buchbinder 2021). The available evidence is insufficient to determine that ESWT leads to an improvement in net health benefit 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 7 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, and 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 of plantar fascia thickness showed no significant difference. Pain intensity after treatment had varied results amongst 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) conducted a meta-analysis that included 9 RCTs and 935 patients to compare the effectiveness of general ESWT, focused shock wave (FSW), and radial shock wave (RSW) to placebo for chronic PF. No serious adverse events were reported. When compared to a placebo, ESWT had better improvements in pain outcomes. 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

Ulusoy et al. (2017) reported the results of an RCT (n=60) comparing the effectiveness of LLLT, ultrasound therapy, and ESWT using magnetic resonance imaging (MRI) for chronic recalcitrant plantar painful heel for 6 months unresponsive to 6 weeks of conservative treatment (e.g., NSAID, home exercise program, and standard insoles). Patients were randomized into 3 treatment groups: Group 1 underwent 15 sessions of LLLT; group 2 underwent 15 sessions of continuous ultrasound therapy; and group 3 underwent 3 sessions of ESWT. The primary outcome was defined as a 60% decrease in heel pain for two VAS measurements. Secondary outcome measures were a functional response to treatment and a reduction in plantar fascial thickness on MRI. At 6-week follow up, the VAS score had significantly decreased and the AOFAS scale scores had significantly improved after treatment in all 3 groups. In the comparison, LLLT and ESWT were found to be more effective than ultrasound therapy, with no significant difference found between LLLT and ESWT in the success rate (VAS score 60%). A significant decrease was found in fascia thickness in all 3 groups after treatment. Side effects were not observed in any patient. Study limitations include small sample size and short duration of follow-up. Study results suggest that LLLT and ESWT may be superior to ultrasound therapy in decreasing pain associated with chronic recalcitrant PF. However additional well-designed studies with larger sample sizes are needed to draw conclusions on treatment effectiveness for this indication.

Washington State Health Care Authority (WSHCA) conducted a Health Technology Assessment (HTA) in 2017 to assess the evidence for the efficacy of ESWT for several musculoskeletal indications including PF, tendinopathies (shoulder, elbow), and knee osteoarthritis. The HTA reviewed electronic databases such as PubMed, Cochrane, and the National Guideline Clearinghouse, from their inception to November 2016 to identify relevant literature. A total of 72 RCTs were reviewed. The limitations of the studies that were noted include potential for risk bias, short-term follow-up, inconsistency of measured outcomes, and lack of high-quality evidence and small sample sizes. The HTA concluded that there is not consistent, high-quality evidence to support efficacy and did not recommend the use of ESWT for any indication.

American College of Foot and Ankle Surgeons (ACFAS) practice guideline indicates that first-line treatment options for plantar heel pain associated with PF include foot padding and strapping, therapeutic orthotic insoles, cortisone injections, and Achilles and plantar fascia stretching for a period of six weeks. Second-line treatment options include continuation of tier one treatments, with consideration for additional therapies, including the use of night splints to maintain an extended length of the plantar fascia and gastrocsoleus complex. The guidelines identified ESWT as a third-tier treatment modality in patients who have failed other interventions, including steroid injection (2010). In an

update to the guidelines, ACFAS issued the consensus that "Extracorporeal shockwave therapy (ESWT) is safe and effective in the treatment of plantar fasciitis" (2017). 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).

American College of Occupational and Environmental Medicine (ACOEM)**.** The updated 2018 ACOEM 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 referred to 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 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 3 times per week, over a period of 3 weeks. Each treatment was combined with silicone insole and stretching exercises. Patients' pain and functional status were evaluated with 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; small sample size; and follow-up of only 3 months.

Cinar et al. (2018) conducted a RCT comparing the efficacy of LLLT and exercise to orthotic support and exercise (usual 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 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 function subscale of American Orthopedic Foot and Ankle Society Score (AOFAS-F) and 12-min walking test including walking speed, cadence, and activity-related pain using VAS. The scores were recorded at baseline, 3rd week, and 3rd month after the treatment. There was a significant improvement in 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 to improve 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. The meta-analysis indicated that compared with control group, VAS score significantly decreased at the end point of the treatment in LLLT group. In addition, this improvement is continued for up to 3 months. However, no significant difference was observed according to the Foot Function Index-pain subscale. The authors concluded that the findings of this meta-analysis indicated that the LLLT in patients with PF significantly relieved the heel pain and efficacy lasted for 3 months following treatment. It is noted that this systematic review and meta-analysis had several limitations including the limited number of studies (six), insufficient power to analyze other factors (such as BMI) that may influence the effect of LLLT treatment, and lack of longer-term follow-up. In addition, the outcome obtained was only based on VAS, and other objective indices (such as heel tenderness index and PF thickness) were not used in all included studies. The authors concluded that LLLT may effectively relieve short-term (i.e., 3 months) heel pain of patients with PF; however, more large-scale, well-designed studies are needed to further clarify long-term efficacy and optimal treatment parameters of LLLT.

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

RFNA or RFL is used to ablate pain pathways and is generally employed for intractable pain that has not responded to conservative measures. There is an overall very low-quality body of evidence that examined RFNA for the treatment of PF. The studies were of fair to very poor quality and limited by small sample sizes, lack of comparison groups, and other methodological flaws. Substantial uncertainty remains regarding the durability of the treatment effect, patient selection, safety, and the comparative efficacy of RFNA compared with 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.

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. Within orthopedics, MSCs are derived mainly from bone marrow. 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 stem cell-based products that are FDA-approved for use in the United States consist of hematopoietic progenitor cells derived from cord blood and is approved for limited use in patients with disorders that affect the hematopoietic system (FDA 2019). 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, 2020). The evidence of effectiveness and safety from methodologically rigorous clinical studies appears to be lacking and its clinical value has not been established in the treatment of PF. MSCs remain an investigational therapy for musculoskeletal tissues (such as muscle, tendon, and fibrous tissue).

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.*' The ISSCR specifically notes that that MSC therapy remains in early experimental stages. (ISSCR 2020).

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 2021).

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
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)
64443	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

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

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.

REFERENCES

Government Agencies
1. Centers for Medicare and Medicaid Services (CMS). Medicare Coverage Database. Available from CMS.
   - Search in all documents: amniotic, amnion, plantar. extracorporeal shock wave therapy for chronic plantar fasciitis.
   - No CMS NCD was identified for chronic plantar fasciitis.
2. Food and Drug Administration (FDA). FDA warns about stem cell therapies. Available from FDA. Updated September 3, 2019.
3. Food and Drug Administration (FDA). Consumer alert on regenerative medicine products including stem cells and exosomes. Available from FDA. Updated July 22, 2020.

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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.*