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| Subject: Plantar Fasciitis Treatments that are Experimental, Investigational and Unproven | | Original Effective Date: 3/11/2019 |
| Policy Number: MCP-338 | Revision Date(s): | |
| MCPC Approval Date: 3/11/2019, 4/23/2020, 2/8/2021 | Review Date: 4/23/2020, 2/8/2021 | |

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DISCLAIMER

This Molina clinical policy is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina clinical policy document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Plantar fasciitis is defined as the inflammation of the plantar fascia which is the thick connective tissue that lies between the heel bone and 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 typically worse in the morning or after a rest period but improves with movement. A diagnosis of plantar fasciitis is made primarily through clinical history and physical examination. Plantar

fasciitis is primarily treated medically, and up to 95% of patients have symptom resolution within 12 to 18 months. Current medical management of plantar fasciitis includes stretching exercises of the foot and calf, avoiding the use of flat shoes and barefoot walking, using prefabricated over-the-counter silicone heel shoe inserts, limiting physical activities such as running, jumping, dancing etc. that can aggravate the condition, short term use of NSAIDS, and injection of the plantar region with glucocorticoids and a local anesthetic. Plantar Fascia release surgery and Extracorporeal Shock Wave Therapy (ESWT) are recommended when all other medical management has failed.

Other unproven minimally invasive treatment strategies include the following:

- Autologous whole blood or platelet-rich plasma injections
- Botulinum toxin injection to the heel
- Complimentary Therapies: topical application of various non-FDA approved creams to the foot
- Cryosurgery or Coblation: a minimally invasive technique for freezing heel tissue
- Low-level laser therapy: application of low level laser treatments to the heel
- Radiofrequency Nerve Ablation (RFNA): application of radiofrequency energy to the heel
- Radiotherapy: the use of radiation therapy to treat heel pain
- Human Amniotic Membrane Injections

POSITION STATEMENT

Minimally invasive therapies for Plantar Fasciitis (i.e. injections of autologous whole blood, platelet-rich plasma, Human Amniotic Membrane, Botulinum toxin), cryosurgery, laser therapy, other complimentary therapies, radiofrequency nerve ablation (RFNA) and radiotherapy techniques) are considered experimental, investigational and unproven due to insufficient evidence in the peer reviewed literature.

SUMMARY OF MEDICAL EVIDENCE⁶⁻³³

Overall, the quality of the evidence is low for minimally invasive therapy for Plantar Fasciitis (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 comparing minimally invasive therapy for plantar fasciitis 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.

Autologous whole blood and platelet-rich plasma (PRP) injections^{6-15 31}

There is a small body of low-quality indicating that functional improvement and pain relief may not differ between PRP and saline, extracorporeal shockwave therapy, endoscopic plantar fasciotomy, or low dose radiation in patients with plantar fasciitis. A small body of low-quality evidence proposes that functional improvement and pain relief may be superior with PRP injections compared with corticosteroid injections in PF patients, however higher quality studies are needed to determine the role of PRP as a treatment for plantar fasciitis.

Yang et al. (2017) performed a meta-analysis (n=9 RCTs/430 patients) to evaluate the current evidence concerning the safety and efficacy of PRP as a treatment for plantar fasciitis compared to steroid treatments. RCTs or prospective cohort studies that compared PRP to a control (e.g., steroid treatment) in patients diagnosed with plantar fasciitis were included. Studies were excluded in which subjects had a traumatic disease, a history of surgical interventions, or systemic disorders

such as rheumatoid arthritis. Outcome measurements included the visual analogue scale (VAS), the Foot and Ankle Disability Index (FADI), American Orthopedic Foot and Ankle Society (AOFAS) scale, and the Roles and Maudsley Score (RMS). Follow-up times were divided into short periods (two–four weeks), intermediate periods (four–24 weeks), and long periods (≥ 24 weeks through 48 weeks). No significant differences in the VAS scores were observed between the two groups in the short term and intermediate term, however, PRP demonstrated better long-term efficacy than steroid treatments ($p=0.03$). No significant differences in the FADI and AOFAS Scale were observed between the groups after 12 weeks. Similarly no significant differences in the RMS were between groups was found after six months. Limitations of this meta-analysis include small sample size and heterogeneity between studies. Additional well-designed, long term studies are needed to establish the role of PRP as a treatment for plantar fasciitis. ¹⁵

Radiofrequency Nerve Ablation (RFNA) ^{16-20 24 25}

There is an overall very low-quality body of evidence suggesting that RFNA is effective for relief of pain associated with plantar fasciitis due to individual study limitations and limited quantity of evidence. Studies provided consistent were each 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, the comparative efficacy of RFNA compared with other minimally invasive treatments, patient selection, and safety.

Osman et al. (2016) conducted a small prospective nonrandomized self-controlled trial ($n=20$) comparing RFNA with pulsed radiofrequency (PRF) for recalcitrant plantar fasciitis. Twenty patients with refractory chronic bilateral plantar fasciitis received PRF to the medial calcaneal nerve for 6 minutes for one heel and thermal radiofrequency (TRF) to the same nerve on the other heel (as their own control) for 90 seconds. Numerical verbal rating scale (NVRS) at waking up from bed and after prolonged walking, and satisfaction score were used for assessment of studied patients at one, 3, 6, 12, and 24 weeks from the intervention. 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. Limitations of this study include lack of randomization; very small sample size; and no long-term f/u. ²⁰

Laser Therapy ²¹⁻²⁶

There is an overall very low-quality body of evidence for laser therapy as a treatment for relief of pain associated with plantar fasciitis due to individual study limitations and limited quantity of evidence. Studies were each of very poor quality and limited by small sample sizes, lack of comparison groups, short term follow-up and other methodological flaws.

Ordahan et al. (2018) compared the efficacy of low-level laser therapy (LLLT) and high-intensity laser therapy (HILT) in 70 patients with plantar fasciitis (PF) who were randomized into either the LLLT (8 men, 27 women; mean age 48.65 ± 10.81 years) or HILT (7 men, 28 women; mean age 48.73 ± 11.41 years) groups. LLLT and HILT were performed three times per week, over a period of 3 weeks. Each treatment combined with silicone insole and stretching exercises. Patients' pain and functional status were evaluated with Visual Analog Scale, 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 Visual Analog Scale, Heel Tenderness Index, and Foot and Ankle Outcome Scores. Three weeks later, both groups showed significant improvement in all parameters ($p < 0.05$). 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 randomization blinded to another method of treatment; small sample size; and follow up of only 3 months. ²¹

Ulusoy et al. (2017) reported the results of an RCT (n=60) comparing the effectiveness of low-level laser therapy (LLLT), therapeutic ultrasound (US) therapy, and extracorporeal shock wave therapy (ESWT) using magnetic resonance imaging (MRI). Inclusion criteria were symptoms of a chronic recalcitrant plantar painful heel for six months unresponsive to 6 weeks of conservative treatment (e.g., nonsteroidal anti-inflammatory drug, home exercise program, and standard insoles). Exclusion criteria included previous local trauma, foot surgery, local steroid injection within the previous three months, diabetes mellitus, and plantar fascial rupture. Patients were randomized into three treatment groups: Group 1 underwent 15 sessions of LLLT; group 2 underwent 15 sessions of continuous US; 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. Data from 54 patients were analyzed for the primary outcome and 52 for the MRI evaluations. At six-week follow up, the VAS score had significantly decreased and the AOFAS scale scores had significantly improved after treatment in all three groups. In the comparison, LLLT and ESWT were found to be more effective than US 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 three groups after treatment. No statistically significant difference was found between the groups in the reduction of the fascia thickness measured on MRI. Side effects were not observed in any patient. Study limitations include small sample size and short follow-up. Study results suggest that LLLT and ESWT may be superior to therapeutic US in decreasing pain associated with chronic recalcitrant plantar fasciitis. However additional well-designed studies with sample sizes are need to draw conclusions on treatment effectiveness for this indication. ²⁶

Other Treatments ²⁷⁻³³

There is an overall very low-quality body of evidence for other treatments (i.e. cryosurgery, Botulinum toxin injections, radiation therapy and complimentary topical ointments) as a treatment for relief of pain associated with plantar fasciitis due to individual study limitations and limited quantity of evidence. Studies were each of very poor quality and limited by small sample sizes, lack of comparison groups, short term follow-up and other methodological flaws.

PROFESSIONAL SOCIETY GUIDELINES ²⁻⁵

The American College of Foot and Ankle Surgeons (ACFAS) practice guideline (2010) indicates that first line treatment options for plantar heel pain associated with plantar fasciitis include foot padding and strapping, therapeutic orthotic insoles, cortisone injections, and Achilles and plantar fascia stretching for a period of six weeks. Second 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 gastrosoleus complex. The guideline recommends that ESWT may be considered as an alternative to traditional surgical approaches for recalcitrant plantar heel pain. ³

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

| 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 |
| 20999 | Unlisted procedure, musculoskeletal system, general |
| 28899 | Unlisted procedure, foot or toes |
| 64640 | Destruction by neurolytic agent; other peripheral nerve or branch |
| 77499 | Unlisted procedure, therapeutic radiology treatment management |

| HCPCS | Description |
|-------|-------------|
| | N/A |

| ICD-10 | Description: [For dates of service on or after 10/01/2015] |
|--------|--|
| M72.2 | Plantar fascial fibromatosis |

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Government Agency

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Professional Society Guidelines

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Other Resources

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 - Radiofrequency Nerve Ablation for Treatment of Plantar Fasciitis. Dec, 2017, Updated April, 2020. [Archived 2021]
 - Comparative Effectiveness Review. Platelet-Rich Plasma for Treatment of Conditions of the Achilles Tendon and Plantar Fascia. March, 2019, updated June, 2020.
 - Human Amniotic Membrane Injections for Treatment of Chronic Plantar Fasciitis. Nov, 2019.
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REVIEW/REVISION HISTORY

3/11/2019: New Policy

4/23/2020: Policy reviewed, no changes.

2/8/2021: Policy reviewed, found one additional Hayes report under reference #34 called Human Amniotic Membrane Injections that are considered I/E.