

Subject: Foot Orthotics for Plantar Fasciitis and Heel Spurs		Original Effective Date:	7/29/10		
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PREFACE

This Medical Guidance 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 exclusions 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 following website: <u>http://www.cms.hhs.gov/center/coverage.asp</u>.

FDA INDICATIONS

A limb orthosis (brace) is a device intended for medical purposes that is worn on the upper or lower extremities to support, correct, or prevent deformities or to align body structures for functional improvement and are regulated by the FDA as Class I devices. Class I devices are subject to the least regulatory control.¹

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

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 medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

CMS has not issued a National Coverage Determination for Foot Orthotics. ²⁹ Federal register CMS guidelines indicate:²⁻⁴ foot orthotics or other supportive devices of the feet are excluded for coverage, except under the following conditions: the shoe is an integral part of a leg brace and its expense is included as part of the cost of the brace, therapeutic shoes for diabetic members, rehabilitative foot orthotics that are prescribed as part of post-surgical or post-traumatic casting care, and prosthetic shoes.

INITIAL COVERAGE CRITERIA

- 1. Custom orthotics *may not be authorized* for plantar fasciitis or heel spurs. Studies of custom foot orthotics in adult or pediatric members *have not proven* effective for plantar fasciitis or heel spurs.⁹⁻²⁵ Therefore, use of custom foot orthotics for these conditions remains investigational, unproven treatment. Investigational treatments are generally not covered by Molina Healthcare plans.
- 2. Prefabricated foot orthosis *may be authorized* for plantar fasciitis or heel spurs when **ALL** of the following criteria have been met.²⁶



Documentation of the following: [ALL]:

- □ Heel pain and symptoms are present for minimally 3 months
- □ Activity limitations have been implemented
- □ Anti-inflammatory medications unsuccessful
- **D** Routine stretching of calf muscles and plantar surface
- □ Appropriate foot ware (e.g., avoidance flat shoes)
- □ intrinsic foot muscle exercises such as toe curls have been performed
- 3. Over-the-counter heel wedges, heel cups arch supports or full length insoles may assist in minimizing abnormal supination or pronation to decrease heel pain.²⁶

CONTINUATION OF THERAPY

N/A

COVERAGE EXCLUSIONS

- Studies of custom foot orthotics in adult or pediatric members *have not proven* effectiveness for plantar fasciitis or heel spurs. Therefore, use of custom foot orthotics for these conditions remains investigational, unproven treatment. (*Non-covered codes L3000-L3031*) Investigational treatments are generally not covered by Molina Healthcare plans.
- There is lack of sufficient data to support the effectiveness of custom foot orthotics in adult or pediatric patients. There is insufficient evidence from prospective or randomized-control trials. There are no differences in the amount of pain reduction or functional improvement associated with custom foot orthoses compared with prefabricated orthoses.^{9-25 33}There is no evidence to support the long term use of custom or prefabricated foot orthoses as an intervention for pain management or to improve function.
- There is no evidence to support the effectiveness of magnetic insoles. ^{8 21 23 31} Magnetic insoles may not be authorized for plantar fasciitis or heel spurs. There is no evidence to support the effectiveness of magnetic insoles.^{21 23 31} The use of magnetic insoles as foot orthotics for these conditions remains an investigational, unproven treatment. Investigational treatments are generally not covered by Molina Healthcare plans.

Refer to covered and non-covered codes in the coding section at the end of this document and refer to the General Information treatment section for conservative treatment measures.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

A foot orthosis is an externally applied device a type of shoe insert that does not extend beyond the ankle and may include heel wedges and arch supports. The goal of orthotic therapy is to reduce strain on the plantar fascia by cushioning and elevating the heel and/or providing medial arch support to assist in decreasing pain and increasing function.¹² They may also correct foot deformities and provide shock absorption to the foot.



Custom fabricated foot orthoses are made for a specific patient from his/her individual measurements and/or pattern (for example a plaster cast, three-dimensional laser scan) and fabricated according to practitioner-prescribed specifications.^{9,27}

Custom fitted are prefabricated items which require individual adjustment, alteration, or assembly for safe and optimal application.²⁷

Direct formed or molded refers to material that is molded over the involved portion of the patient's body and used as an essential part of the device.²⁷

Molded to patient model is a custom manufactured item individually fabricated over a positive model of the patient, based on three-dimensional negative impression or digital scanning.²⁷

Prefabricated orthosis refers to a device that has been manufactured from standard molds or patterns.²⁷

Plantar Fasciitis is a painful inflammatory process of the plantar fascia.^{5,6} The predominant symptom is pain in the plantar region of the foot that increases when walking.⁸ The plantar fascia is a thick fibrous band of connective tissue originating on the bottom surface of the calcaneus (heel bone) and extending along the sole of the foot towards the five toes. It has been reported that plantar fasciitis is responsible for approximately one million patient visits to a physician in the United States annually,⁸ and account for 11 to 15% of all foot symptoms requiring professional care among adults.⁷ The highest incidence occurs between 40 and 60 years of age amongst the general population and younger in runners, athletes and dancers.^{7,8} One third of the cases have reported bilateral symptoms. The etiology is not clearly understood. Case control studies have reported multiple risk factors contributing to plantar fasciitis including flat foot or high-arched foot, obesity, prolonged standing or jumping, reduced ankle dorsiflexion, and bone spurs in the heel. ^{7,8} Plantar fasciitis has also been reported in people with systemic inflammatory arthritis.²⁴

Bone spurs or calcaneal spurs have conflicting literature regarding etiology of the condition and no generally standard approved treatment based upon high quality clinical studies.^{6,8} A calcaneal spur is a small bony calcification that develops on the calcaneus heel bone and extends across the entire width of the calcaneous. The apex of the spur is embedded in the plantar fascia. Heel spurs are typically asymptomatic; pain may occur when the apex is angled downward by depression of the long arch. Acute painful heel spurs may be present in various systemic diseases, such as reactive arthritis, rheumatoid arthritis, or ankylosing spondylitis. Calcaneal spurs are present in 50 percent of patients with a painful heel and 16 percent of asymptomatic patients.¹¹

GENERAL INFORMATION

Summary of Medical Evidence

There are no differences in the amount of pain reduction or functional improvement associated with custom foot orthoses compared with prefabricated orthoses.⁹⁻²⁵ There is no evidence to support the long term use of custom or prefabricated foot orthoses as an intervention for pain management or to improve function. Studies have shown short term pain reduction and functional improvement for up to 3 months.

There is no significant evidence to define standard of care or treatment of choice in treating plantar fasciitis or heel spurs.⁷ There is no consensus on the efficacy of any particular conservative treatment regimen.⁶ There is



agreement that ninety to ninety-five percent of patients have success with conservative treatment.^{6,11} A period of six to 12 months of conservative treatment may be necessary to return to premorbid activity in young athletes and adults. A survey of patients treated conservatively for plantar heel pain had spontaneous resolution of pain after many months.⁷

Custom versus Prefabricated Foot Orthoses

Previous review of studies for foot pain conditions have suggested improvement in outcomes.^{10,24} These studies have been based on anecdotal evidence and have methodological flaws such as a lack of using other treatments as controls for comparison; patient satisfaction measures that may have been more reflective of quality service than treatment outcomes; and the possibility of symptom resolution being due to limiting certain activities or other measures implemented while orthotics are used. The lack of sufficient evidence prevents any kind of determination on whether customized orthoses are more effective than prefabricated devices.

One randomized trial without intention-to-treat analysis suggested prefabricated shoe inserts are more likely to produce improvement than custom polypropylene orthotic devices or no shoe inserts.¹³ A total of 236 participants > 16 years of age with symptomatic proximal plantar fasciitis less than 6 months were instructed in plantar fascia-stretching and Achilles-tendon stretching and randomized to one of 5 groups: stretching only, silicone heel pad plus stretching, felt pad and stretching, rubber heel cup plus stretching, and custom-made polypropylene orthotic device plus stretching. Two hundred participants (85%) at 8 weeks were analyzed with an improvement rate of 95% with silicone shoe inserts, 88% with rubber inserts, 81% with felt inserts, 68% with custom orthosis and72% with stretching alone. Prefabricated inserts were associated with greater improvement than stretching alone (P=0.022) compared with custom orthotic use and stretching (p = 0.0074). The authors concluded that when used in conjunction with a stretching program, a prefabricated shoe insert is more likely to produce improvement in symptoms as part of the initial treatment of proximal plantar fasciitis than a custom polypropylene orthotic device.¹³

One randomized-control trial demonstrated only small short-term benefits in function and pain levels with borderline statistical significance using prefabricated foot orthoses.¹⁴ A total of 135 patients with plantar fasciitis were randomized to sham orthoses (thin foam, soft) versus prefabricated orthoses (firm foam) versus customized orthoses (semirigid plastic) for 12 months. At 3 months, mean pain score was 8.7 points better with prefabricated orthoses (95% CI 0.1 to 17.6, p= 0.05) and 7.4 points better with customized orthoses (95% CI 1.4 to 16.2, p =0.01) compared with sham orthoses at 3 months using 0-100 scales. Mean function score for prefabricated orthoses was 8.4 points better (95% CI 1 to 15.8, p =0.03) and 7.5 points better with customized orthoses (95% CI 0.3 to 14.7, p = 0.040) compared with sham treatment. There were no significant differences in pain or function at 12 months.

A randomized trial of 142 adults without intention –to-treat analysis were randomized to prefabricated versus customized foam foot orthoses and evaluated at 4 and 8 weeks.¹⁵ Similar pain improvement in patients with uncomplicated plantar fasciitis were demonstrated when comparing prefabricated and customized foam foot orthoses. Seventeen participants were lost to follow-up (12%). Improvement in pain was demonstrated in both groups when compared to baseline (p < 0.05) but no significant differences were noted between the two groups.



An open label randomized trial of 103 patients (85 patients completed the study) with plantar fasciitis were randomized to 1 of 3 treatments for 3 months: mechanical treatment (low-dye taping for 1 month then rigid custom orthosis for 2 months), anti-inflammatory treatment etodolac plus corticosteroids injections), or accommodative treatment (viscoelastic heel cup).¹⁶ Mechanical treatment (taping then orthosis) may be more effective than anti-inflammatory or accommodative (heel cup) treatment as 70% of the mechanical group rated functional outcomes as excellent at 3 months versus 33% of the anti-inflammatory and 30% accommodative groups (p = 0.005, NNT).

A trial of 255 patients with plantar fasciitis were randomized to custom-made orthoses versus over-the counter arch supports versed tension night splints for up to 3 months.¹⁷ The study limitation included high withdrawal rates of 7% in the orthoses group and 26% in the night splint group and the trial was without intention-to-treat analysis. The authors concluded arch supports appeared as effective as custom orthotics or night splints. There were no significant differences between groups in pain during the day or pain on the first step. There was a significant difference among the three groups regarding early withdrawal resulting from continued severe pain, noncompliance, or inability to tolerate the device.

A small randomized trial of 43 patients with plantar fasciitis was randomized to foot orthoses versus night splints versus foot orthoses with night splints.¹⁸ A twelve week follow-up for all groups had significant pain reduction when compared to baseline (p < 0.03). The one year follow-up results revealed a significantly higher pain reduction in foot orthoses and foot orthoses with night splints than using night splints alone (p < 0.01). The authors concluded foot orthoses may be more effective than night splints alone in reducing pain. The results are statistically underpowered limiting the validity of the results.

A small randomized trial of 48 patients with plantar heel pain were randomized to functional orthosis (corrects biomechanical instability) versus accommodative orthosis (provides cushioning and padding for 8 weeks).¹⁹ The study had a high dropout rate with 35 patients or 73% completing the study. The functional orthosis were associated with a significant increase in foot function and decrease in foot pain at 8 weeks. The accommodative orthoses had significant reduction in foot pain at 4 weeks but not at the 8 week interval. The authors concluded functional orthoses may be more effective than accommodative orthosis for plantar heel pain. The results are statistically underpowered limiting the validity of the results.

A small study of 50 patients with plantar fasciitis for minimally 4 weeks but less than 12 weeks were randomized into patients using AirHeel (Aircast, Inc) and 1st Step prefabricated foot inserts. Standard weight bearing radiographs were obtained.²⁰ There were no clinical outcomes assessed which lacks direct evidence of effectiveness. The authors concluded a compression device reduces midstance force more than prefabricated foot insert. The results are statistically underpowered limiting the validity of the results.

Magnetic Insoles

There is no evidence to support the effectiveness of magnetic insoles.^{21,22,23} A randomized trial of 101 adults with plantar heel pain for minimally 30 days were randomized to receive static bipolar magnets embedded in cushioned insoles versus sham magnets worn daily (minimally 4 hours daily for 4 days a week) for 8 weeks.²¹ There were no significant differences in improvements in morning foot pain intensity or foot pain interference with activity. There were minimal differences between the magnet group versus nonmagnetic groups in



improvements at 4 weeks (31% versus 44% (p =0.19) and 8 weeks (35% versus 33%, p =0.78). Compliance was 92% in the magnetic group versus 98% in the nonmagnetic group in wearing insoles on most days at 4 weeks and 87% versus 83% at 8 weeks. Reports problems with the insoles at 4 weeks was 13% in the magnetic group versus 27% in the nonmagnetic group, p=0.11) (e.g., cosmetic breakdown of insole surface material and tightness of the shoe. Adjustments for baseline differences did not change outcomes.

A second randomized double-blind controlled trial of 89 participants confirmed the results that the magnetic soles were not clinically effective.²² A systematic review of static magnetics to reduce pain included three randomized trials for foot pain.²³ The authors also concluded the evidence does not support the use of static magnets for pain relief and cannot be recommended as an effective treatment.

Treatment Recommendations for Plantar Fasciitis and Calcaneal Spurs

First line conservative treatment involves stretching ^{39 40 41}, pain management and inflammation (e.g., two to three weeks of short term nonsteroidal anti-inflammatory),^{8,28} appropriate foot gear, six months²⁶ of activity limitation^{8,11,25,26,28} to avoid pain with limitation of weight bearing (e.g., excessive running, jumping, dancing etc), avoiding flat shoes and bare-foot walking,⁸ weight loss when indicated,^{26,28} and intrinsic muscle exercises such as toe curls.^{11,25} Second line conservative treatment involves enhanced exercises with possible physical therapy. Low dye taping is used to enhance arch support and decrease the pull on the plantar fascia.^{26,28} Night splints have shown to be somewhat effective but are cumbersome. Therapy compliance to night splints is poor but should be considered in patients with persistent symptoms.^{26,28} Low dye taping is recommended and preferred over orthotics for plantar fasciitis.¹¹ Over-the-counter heel wedges, heel cups arch supports or fell length insoles may assist in minimizing abnormal supination or pronation to decrease heel pain.²⁶

There are no studies that provide specific results to support recommendations specifically for calcaneal spurs. Cutout heel pads have been recommended.⁸

Treatment options include taping, strapping, injection therapy, Unna boot, walking fracture splint, cast to resist foot elongation, NSAIDs, roller-soled shoes, non-weight bearing using crutches, a weight loss program, reduced activity (activity restriction), physical therapy (e.g., ice, stretching, ultrasound, etc.), night splints, temporary foot orthoses, prefabricated foot orthoses

Hayes, Cochrane, UpToDate, MD Consult etc.

Hayes does not have a Directory Report on the topic of foot orthotics for plantar fasciitis and heel spurs.

Cochrane

A Cochrane systematic review evaluated all randomized control trials and controlled clinical trials that included custom foot orthoses for any type of foot pain.⁹ Eleven randomized trials and controlled clinical trials with methodological limitations in 1,332 participants' evaluated custom made foot orthoses for various types of foot pain. Custom foot orthoses were compared with no intervention, sham orthoses, prefabricated orthoses, night splints, surgery, standardized interventions provided to all groups, and combined mobilization-stretching-manipulation. Foot pain associated with plantar fasciitis was evaluated in 5 trials with 691 participants. The trials were considered to have a high risk of potential bias. The follow-up periods ranged from one month to



three years. The use of custom orthoses in plantar fasciitis suggested that pain may not be reduced any more than when compared with any other treatment (e.g., non-custom orthotics, stretching exercises, night splints, fake foot orthoses, or a combination of stretching, mobilization, or manipulation). The authors concluded that there is limited evidence to make decisions regarding prescription of custom orthoses for the treatment of foot pain. There is limited evidence of short term reduction of pain in painful pes cavus, foot pain in juvenile idiopathic arthritis, rheumatoid arthritis, plantar fasciitis and hallux valgus.

Another Cochrane systematic review was conducted to identify and evaluate the evidence for effectiveness of treatments for plantar heel pain. Nineteen randomized trials involving 1626 adult participants evaluated interventions for plantar heel pain in adults. Trial quality was generally poor, and pooling of data was not conducted. All trials measured heel pain as the primary outcome. Seven trials evaluated interventions against placebo/dummy or no treatment. There was limited evidence for the effectiveness of topical corticosteroid administered by iontophoresis, i.e. using an electric current, in reducing pain. There was some evidence for the effectiveness of injected corticosteroid providing temporary relief of pain. There was conflicting evidence for the effectiveness of low energy extracorporeal shock wave therapy in reducing night pain, resting pain and pressure pain in the short term (6 and 12 weeks) and therefore its effectiveness remains equivocal. In individuals with chronic pain (longer than six months), there was limited evidence for the effectiveness of dorsiflexion night splints in reducing pain. There was no evidence to support the effectiveness of therapeutic ultrasound, low-intensity laser therapy, exposure to an electron generating device or insoles with magnetic foil. No randomised trials evaluating surgery, or radiotherapy against a randomly allocated control population were identified. There was limited evidence for the superiority of corticosteroid injections over orthotic devices. The authors concluded that although there is limited evidence for the effectiveness of local corticosteroid therapy, the effectiveness of other frequently employed treatments in altering the clinical course of plantar heel pain has not been established in randomised controlled trials. At the moment there is limited evidence upon which to base clinical practice. Treatments that are used to reduce heel pain seem to bring only marginal gains over no treatment and control therapies such as stretching exercises. Steroid injections are a popular method of treating the condition but only seem to be useful in the short term and only to a small degree. Orthoses should be cautiously prescribed for those patients who stand for long periods; there is limited evidence that stretching exercises and heel pads are associated with better outcomes than custom made orthoses in people who stand for more than eight hours per day. Well designed and conducted randomised trials are required.³³

<u>UpToDate</u>

In a report called Plantar fasciitis and other causes of heel pain⁸ this condition is described as a painful disorder that is associated with degenerative and sometimes chronic inflammatory changes in the affected tissue. It has a good prognosis, and with conservative treatment, a complete resolution of symptoms usually occurs within one year. Many types of treatments have been used for plantar fasciitis, but few have been rigorously validated in large clinical trials. The following initial interventions are recommended:

- Performing of stretching exercises for the plantar fascia and calf muscles, which the patient can do at home
- Avoiding the use of unsupportive shoes and barefoot walking
- Using prefabricated, over-the-counter, shoe inserts
- Decreasing physical activities that aggravate symptoms



• Prescribing or recommending a short-term trial (two to three weeks) of NSAIDs

The use of magnetic insoles has not been found to provide additional benefit compared with nonmagnetic insoles. ⁸

Professional Organizations

The Orthopedic section of the <u>American Physical Therapy Association (APTA)</u> evidence-based practice guidelines (2008) for orthopedic physical therapy management interventions for patients with musculoskeletal impairments recommend calf muscle and plantar fascia stretching, calcaneal or low-dye taping, and short term use of orthoses for up to 3 months. Night splints are recommended for consideration in patients with symptoms greater than 6 months in duration.²⁵

<u>The American College of Foot and Ankle Surgeons</u> Clinical Practice Guideline (2010) for the diagnosis and treatment of heel pain outlines the following treatment options: 30

- Padding and strapping of the foot
- Therapeutic orthotic insoles
- Oral inflammatory medication
- Cortisone injections

<u>The Academy of Ambulatory Foot and Ankle Surgery</u> (AAFAS) Guideline for Heel Spur Syndrome ³² includes recommendations for nonsurgical treatment: padding and strapping (taping), orthotics, heel cup, shoe modifications, oral anti-inflammatory medications (NSAIDs), anti-inflammatory injectables (i.e., corticosteroids), injection of local anesthetics (i.e., peripheral nerve block), analgesics, physical therapy, and extracorporeal shockwave therapy.

<u>The Occupational Medicine Guidelines (2011)</u>³¹ practice guideline on ankle and foot disorders recommend certain treatment options for appropriate patients with plantar fasciitis but caution that there is limited evidence that the intervention may improve important health and functional benefits. Treatments include: orthotic devices, heel taping, Botulinum toxin A injection for select patients and glucocorticosteroid injections for short-term relief. Magnetic insoles are not recommended.

CODING INFORMATION		
СРТ	Description	
	N/A	

HCPCS	Description
L3000-	Foot inserts, removable custom (NOT Covered, Custom)
L3031	
L3040 –	Foot arch supports, removable or nonremovable (Covered after 3 months) therapy)
L3090	
L3100	Hallus-valgus night dynamic splint (Covered after 3 months)



L3300-	Heel Lifts (Not covered)
L3334	
L3340-	Foot wedges (Covered after 3 months)
3390	
L3430	Heel, counter, plastic reinforced (Covered after 3 months)
L3440	Heel, counter, leather reinforced (Covered after 3 months)
L3450	Heel, SACH cushion type (Covered after 3 months)
L3455	Heel, new leather, standard (Not Covered)
L3460	Heel, new rubber, standard (Not Covered)
L3465	Heel, Thomas with wedge (Not Covered)
L3470	Heel, Thomas extended to ball (Not Covered)
L3480	Heel, pad and depression for spur (Covered after 3 months)
L3485	Heel, pad, removable for spur (Covered after 3 months)
L3500 -	Miscellaneous shoe additions, transfers, or replacements (Not covered)
L3649	

ICD-9	Description
726.73	Calcaneal spur
728.71	Plantar fascial fibromatosis

ICD-10	Description
M77.30	Calcaneal spur unspecified foot
M77.31	Calcaneal spur right foot
M77.32	Calcaneal spur left foot
M72.2	Plantar fascial fibromatosis

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