

Subject: Foot Orthotics for Pes Planus/ Talipes Planus in Adults and Pediatrics (Flat feet)		Original Effective Date: 4/28/10
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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: <http://www.cms.hhs.gov/center/coverage.asp>.

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.³⁸ Federal register CMS guidelines indicate:³⁴⁻³⁶ 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

Studies of foot orthotics in adult or pediatric members **have not proven** effectiveness for pes planus/talipes planus (flatfoot). Therefore, use of foot orthotics for these conditions remains investigational, unproven treatment. Investigational treatments are generally not covered by Molina Healthcare plans.

CONTINUATION OF THERAPY

N/A

COVERAGE EXCLUSIONS

Studies of foot orthotics in adult or pediatric members *have not proven* effectiveness for pes planus/talipes planus (flatfoot). Therefore, use of foot orthotics for these conditions remains investigational, unproven treatment. Investigational treatments are generally not covered by Molina Healthcare plans.

There is lack of sufficient data to support the effectiveness of foot orthotics in adult or pediatric patients. There is insufficient evidence from prospective or randomized-control trials. The results from the adult pes planus studies are statistically underpowered limiting the validity of the results. Conservative treatment measures have been reported in the literature for painful pes planus to include rest, anti-inflammatory medications, activity modification, and stretching exercises.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

A foot orthosis is a type of shoe insert that does not extend beyond the ankle and may include heel wedges and arch supports. The goal of treating conditions with foot orthoses is to decrease pain and increase function. They may also correct some foot deformities and provide shock absorption to the foot.

Custom (custom-made) foot orthoses are defined as contoured, removable in-shoe devices that are molded or milled from an impression of the foot (for example a plaster cast, three-dimensional laser scan) and fabricated according to practitioner-prescribed specifications.⁶

Prefabricated orthosis can be modified (e.g., trimmed, bent or molded) for use by a specific patient and is then considered a custom-fitted orthosis. An orthosis that is made from prefabricated components is considered a prefabricated orthosis. Any orthosis that does not meet the standard definition of custom-fabricated is considered to be a prefabricated device.

GENERAL INFORMATION

Summary of Medical Evidence

Adult Pes Planus (Flat Foot)

There is no universally accepted definition of adult flatfoot. The American College of Foot and Ankle Surgery (ACFA) has defined adult flatfoot as a foot condition that persists or develops after skeletal maturity and is characterized by partial or complete loss (collapse) of the medial longitudinal arch.⁸ Presentation may be asymptomatic or symptomatic (e.g., pain, tenderness, cramping, changes in walking patterns, outward tilting of heel, shoe difficulties) with conditions ranging from mild limitations to severe disability and pain.

Summary of Medical Evidence for Orthoses in Adult Flatfoot

There is insufficient evidence from the peer reviewed literature to support the effectiveness of foot orthoses in the treatment of adult flatfoot. There were a limited number of studies available.²⁸⁻³³ These studies have been

based on anecdotal evidence and have methodological flaws such as a lack of using other treatments as controls for comparison and small number of participants.

One small randomized controlled trial of 36 adults with Stage I or II tibialis posterior tendonopathy were randomly assigned to 1 of 3 groups in a 12 week program.³¹ 1) orthoses wear and stretching 2) orthoses wear, stretching, and concentric progressive resistant exercise, 3) orthoses wear, stretching and eccentric progressive resistant exercise. All groups demonstrated improvement following the interventions. The most improvements were noted in the third group. Orthoses was not evaluated alone or compared with other treatment interventions to determine effectiveness and the study size was small. Forty nine patients with posterior tibial tendon dysfunction were treated with foot orthoses. Forty feet were treated with molded ankle-foot orthosis, and 13 feet were treated with University of California Biomechanics Laboratory shoe inserts with medial posting.³⁵ The mean follow-up was 20.3 months. The study reported that 67% of patients had good to excellent results based on pain, function, use of assistive devices, distance of ambulation, and patient satisfaction. However, one patient requested surgical intervention rather than continued orthosis use. Thirty-three percent of the patients discontinued using orthosis at the time of follow-up examination. Three patients were unable to wear the orthosis due to other medical conditions. Nine patients stopped wearing the orthosis due to inconvenience or discomfort. Four patients required surgery due to poor tolerance of the orthosis. Another study included a combination of therapies with the use of orthosis (plantarflexion activities, high-repetition exercises, tendon stretching, and a home exercise program).³² These therapeutic modalities were not compared for effectiveness.

A retrospective cohort study (2011) was performed that focused on nonoperative measures, including bracing, physical therapy, and anti-inflammatory medications, used to treat adult-acquired flatfoot in 64 consecutive patients. The results revealed the incidence of successful nonsurgical treatment to be 87.5% (56 of 64 patients), over the 27-month observation period. Overall, 78.12% of the patients with adult-acquired flatfoot were obese (body mass index [BMI] ≥ 30), and 62.5% of the patients who failed nonsurgical therapy were obese; however, logistic regression failed to show that BMI was statistically significantly associated with the outcome of treatment. The use of any form of bracing was statistically significantly associated with successful nonsurgical treatment (fully adjusted OR = 19.8621, 95% CI 1.8774 to 210.134), whereas the presence of a split-tear of the tibialis posterior on magnetic resonance image scans was statistically significantly associated with failed nonsurgical treatment (fully adjusted OR = 0.016, 95% CI 0.0011 to 0.2347). The authors concluded that the results of this investigation indicate that a systematic nonsurgical treatment approach to the treatment of the adult-acquired flatfoot deformity can be successful in most cases.⁴⁰

Jung et al. (2011) examined the effects of foot orthoses and a short-foot exercise intervention on the cross-sectional area (CSA) of the abductor hallucis (AbdH) muscle and strength of the flexor hallucis (FH) in subjects with pes planus. Twenty-eight subjects with pes planus were randomly assigned to the foot orthosis (FO) group or the combined foot orthosis and short-foot exercise (FOSF) group for an 8-week intervention. The CSA of the AbdH muscle and the strength of FH were assessed before and after intervention. Data were analyzed using a

mixed-model ANOVA. Significant group by intervention interaction effects were observed in CSA of the AbdH ($p=0.009$) and strength of the FH ($p=0.015$). The results of the post hoc paired t-test showed that the CSA of the AbdH muscle and the strength of the FH significantly increased after the intervention in both groups ($p=0.000$). The mean CSA of the AbdH muscle and the strength of FH were significantly greater in subjects in the FOSF group compared with subjects in the FO group (mean difference of FO vs. FOSF=13.61 mm²) in CSA of AbdH muscle; 0.90 kgf in strength of FH; $p=0.008$). Results from this study demonstrate that foot orthoses combined with short-foot exercise is more effective in increasing the CSA of the AbdH muscle and the strength of FH compared with foot orthoses alone. The authors concluded that foot orthoses combined with short-foot exercise are recommended for improving strength of AbdH muscle in subjects with pes planus.⁴²

Pediatric Pes Planus (Flat Foot)

There is no universally accepted definition of pediatric flatfoot.¹⁸ The American College of Foot and Ankle Surgery indicate that flatfoot may exist as an isolated pathology or as a part of other clinical entities that include generalized ligamentous laxity, neurologic and muscular abnormalities, genetic conditions and syndromes, and collagen disorders.² A further distinction is made between rigid flatfoot, which is typically associated with underlying pathology, and flexible flatfoot, characterized by an arch that appears normal when nonweightbearing but flattens on stance. Flexible flatfoot may also be physiologic or nonphysiologic. Nonphysiologic flatfoot is further defined as symptomatic or asymptomatic.^{2,18}

Rigid flatfoot may be associated with underlying pathology.^{2,18} Flatfoot can also be divided into congenital convex pes valgus, flatfoot associated with tarsal coalition, peroneal spastic flatfoot without tarsal coalition and iatrogenic flatfoot. Skew foot is an uncommon disorder characterized by severe rear foot pronation and rigid forefoot adductovarus.² Skew foot has characteristics that resemble a type of flat foot described as a z foot or serpentine foot. Flat feet associated with other issues are caused by neurologic disease, collagen vascular disease, muscular disease, and syndromes.¹⁸ There is no progressive relationship between flexible flatfoot and rigid deformities. Simple flatfoot does not become congenital convex pes valgus. Flexible flatfoot does not progress to rigid deformity in most cases.

Orthotic Intervention for Pediatric Flexible Flatfoot

There are no long-term longitudinal studies with follow-up into adulthood of patients with asymptomatic flexible pes planus that went untreated; there are no convincing data that shoe inserts or modifications alter the final structure of the foot.²⁰ One study concluded that corrective shoes and inserts worn for 3 years did not change the course of flexible pes planus in children. Several studies have shown no correlation with the configuration of arches and pain as being a source of disability from pediatric flatfoot into adulthood.

One study of 441 participants suggested that flat feet of various types are common in infants, children, and within the normal range in adults.¹⁰ A study involving 579 school children with a mean age of nine identified

17% of the children with moderate to severe flexible flatfoot.¹¹ Another study followed 125 beginning walkers for four years and determined that all normal toddlers had primarily flexible flatfeet and that foot arches developed regardless of footwear.¹² Hyperpronation was identified in 78% of five-year-olds and the authors concluded that this condition is normal for this age group.

Researchers evaluated 1181 schoolchildren between the ages of 4 and 13 to determine the prevalence of flatfeet and estimate the number of unnecessary treatments for flatfeet.¹³ The sample was separated into three foot grades: grade 1 in which support of the lateral edge of the foot is half that of the metatarsal support; grade 2 in which the support of the central zone and forefoot are equal; and grade 3 in which the support in the central zone of the foot is greater than the width of the metatarsal support. Only 2.7% of the children evaluated met the diagnostic criteria for flat feet but orthopedic treatment was given to 14% (168) of the children. Of the 2.7% diagnosed with flatfoot only 28 % of these children were being treated. The same cohort study revealed under treatment and overtreatment of flatfeet. A second of 835 children between the ages of 3 and 6 found that the prevalence of flatfoot was approximately 44%, was more common in obese children and boys, and decreased with age. The researchers concluded that more than 90% of treatments were unnecessary in the children evaluated.¹⁴

Flexible flatfeet in children are still treated with orthotics and operative procedures by some physicians who believe such treatment will prevent disability in adult life. There is little evidence to suggest that flexible flatfoot in infants or children result in long-term problems or disability in adults.⁷ A prospective study of 246 US Army Infantry trainees followed over an intense 12 week training program found that the 20% of trainees with the flattest feet had lower risk of injury than those with higher arches.¹⁵ Ninety-nine adult male and female physically active grocery-store employees were studied.¹⁶ Half-weight-bearing footprints were made, and leg and foot pain questionnaires were scored for each subject. No relationship was found between arch configuration and pain scores. A third study evaluated the prevalence and risk factors for flat foot among 2100 Saudi Arabian army recruits between 18 and 21 years of age.¹⁷ The prevalence of flat foot was 5%. A case controlled logistic regression analysis of risk factors was performed that identified family history, wearing shoes during childhood, urban residence and obesity were significantly associated with flat feet. No complaints were reported among the flatfoot trainees. The authors concluded that flatfoot did not appear to be associated with disability. There is no scientific evidence to support that prophylactic use of orthotics for flat-footed athletes, prevents future injury.

Three randomized-control trials have studied orthotic intervention in children with flatfoot.³⁻⁵ Two of the three studies that looked at flexible flatfoot reported no significant differences between treatment and control groups.^{3,5} One study reported significantly improved pain, function, and quality of life in children with juvenile idiopathic arthritis.⁴

The first study enrolled one hundred and twenty-nine children between the ages of one and six who had been referred by pediatricians, and for whom the radiographic findings met the criteria for flatfoot, were randomly assigned to one of four groups: Group I, controls; Group II, treatment with corrective orthopedic shoes; Group III, treatment with a Helfet heel-cup; or Group IV, treatment with a custom-molded plastic insert.³ Children with neurological conditions (cerebral palsy or muscular dystrophy) or a syndrome associated with excessive laxity of joints (Down's or Ehlers-Danlos) were eliminated. Pain relief and changes in gait could not be accurately quantified and were not included in the study analysis. All of the patients in Groups II, III, and IV

had a minimum of three years of treatment, and ninety-eight patients whose compliance with the protocol was documented completed the study. Analysis of radiographs before treatment and at the most recent follow-up demonstrated a significant improvement in all groups ($p < 0.01$), including the controls, and no significant difference between the controls and the treated patients ($p > 0.4$). The authors concluded that wearing corrective shoes or inserts for three years does not influence the course of flexible flatfoot in children.

The second randomized-control trial had 40 participants, 5 to 19 years of age, with juvenile idiopathic arthritis and foot pain resulting from various orthopedic conditions were randomized to one of three groups receiving: 1) custom-made semirigid foot orthotics with shock absorbing posts ($n=15$), 2) off-the-shelf flat neoprene shoe inserts ($n=12$), or 3) supportive athletic shoes with a medial longitudinal arch support and shock absorbing soles worn alone ($n=13$).⁴ Foot pain and functional limitations were measured using the Pediatric Pain Questionnaire-visual analog scale (VAS), Timed Walking, Foot Function Index (FFI), and the Physical Functioning Subscale of the Pediatric Quality of Life Inventory.TM Measures were evaluated at baseline (before wearing the intervention) and at 3 months' follow-up. Children in the orthotics group showed significantly greater improvements in overall pain ($p=0.009$), speed of ambulation ($p=0.013$), activity limitations ($p=0.002$), foot pain ($p=0.019$), and level of disability ($p=0.024$) when compared with the other two groups. Neither the off-the-shelf shoe inserts or the supportive athletic shoes worn alone showed significant effect on any of the evaluation measures except for reduction of pain with the supportive athletic shoes (paired t test, $p=0.011$). The authors concluded that custom made semirigid foot orthotics with shock-absorbing posts significantly improve pain, ambulation speed, and self-rated functional ability and activity compared with off the shelf, prefabricated shoe inserts or supportive athletic shoes worn alone. A study limitation outlined that only one type of custom and one prefabricated shoe insert was evaluated. Materials for shoe insert vary providing differing levels of support. A semirigid custom insert was used versus a prefabricated neoprene shoe insert.

A randomized parallel, single-blinded, controlled trial of custom-made and ready-made orthoses was conducted in children between the ages of 7 and 11 years with bilateral flexible excess pronation. The diagnoses was based upon navicular drop and calcaneal eversion.⁵ Measured outcomes included self-perception, gross motor proficiency, exercise efficiency, and pain. Measurements were evaluated at baseline, and 12 months. One hundred sixty of the 178 children continued to the end of the trial. None of the group comparisons were statistically significant. A sub-group analysis of those presenting with pain found no significant difference at 3 or 12 months. The authors concluded that no evidence is available from the study to justify the use of in-shoe orthoses in the management of flexible excess foot pronation.

A retrospective study (2011) was performed to compare a group of children who followed a rehabilitative programme versus a historical group of children who had been treated with insoles and orthopaedic footwear. Over a 2 year period (1995-1997), 300 children (mean age was 3.4-184 male, 116 female) with bilateral flexible flatfoot (600 feet) were recruited and underwent a rehabilitative programme for a mean period of 2.75 years. The feet were classified according to Viladot's method: 386 feet presented a type III degree deformity and 214 feet presented a type II degree deformity. The rehabilitative programme consisted of simple therapeutic exercises, which could be easily learnt by both patients and their caregivers. These children were compared to a historical group of children (674 feet) who had been treated in our department for infantile flexible flatfoot with the use of orthosis. In these groups, 396 feet presented a type III degree deformity and 278 feet presented a type

II degree deformity. In the group of children who underwent the rehabilitative protocol, during follow-up at the age of eight, 352 of the 386 type III degree feet could be classified as normal and 210 of the 214 type II degree cases became normal. In the historical cohort of children treated with orthosis, at the age of eight, 214 of the 396 type III degree feet could be classified as normal; and 248 of the 278 type II degree cases became normal. The authors reported that comparing the percentage of success (changing from type III or II degree to type I or N) in the two groups (children treated with rehabilitation and children treated with orthosis), the rehabilitative approach seems to be more effective. Probably it has a marginal influence on the natural history of paediatric valgus flexible flatfoot even though it plays a role in maintaining good flexibility of the flatfoot thus limiting functional impairment.⁴⁰

Mackenzie et al. performed a systematic review (2011) to evaluate the effect of pediatric foot orthoses from assessment of the current literature. Inclusion criteria were peer-reviewed journal articles, publication date from 1970 onwards, in the English language. Exclusion criteria were surgery interventions, adult subjects, rigid flat foot, articles based on opinion. A structured Quality Index was used to evaluate the research quality of articles. Three reviewers independently assessed the studies with disputes resolved by majority consensus. Studies were then grouped according to the outcome measures used. : Thirteen articles, from an initial 429, met the criteria for quality evaluation. The mean Quality Index score was 35% (range: 13% to 81%), indicative of generally poor and varying methodological quality. The low quality of the studies negates definitive conclusions. Only 3/13 quality evaluations scored >50%; hence, evidence for efficacy of nonsurgical interventions for flexible pediatric flat feet is very limited. Future research needs validated foot type assessment, applicable outcome measures for the intervention, the use of control groups, allowance for independent effects of footwear, age range comparisons, larger samples, and prospective, longer follow-up. The authors concluded that there is very limited evidence for the efficacy of nonsurgical interventions for children with flexible flat feet. Clinicians need to consider the lack of good-quality evidence in their decision-making for the management of pediatric flat foot.⁴³

Custom Foot Orthoses

Previous studies for foot pain conditions have suggested improvement in outcomes.⁹ 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.

Hayes, Cochrane, UpToDate, MD Consult etc.

Hayes does not have a Directory Report on the topic of foot orthotics for Pes Planus.

A Cochrane systematic review (2008) evaluated all randomized control trials and controlled clinical trials that included custom foot orthoses for any type of foot pain.⁶ Eleven trials with 1,332 participants were included. Plantar fasciitis pain were identified in five trials, three in rheumatoid arthritis and one each for foot pain in pes cavus, juvenile idiopathic arthritis, and hallux valgus. 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. The follow-up periods ranged from one month to three years. Some of the studies showed improvement in pain for a short follow-up period of three months in pes cavus (high arch) compared with fake orthoses; and rear foot rheumatoid arthritis pain in adults compared with no treatment but not when compared with prefabricated neoprene inserts; foot pain in juvenile idiopathic arthritis compared with supportive shoes but not when compared with neoprene prefabricated shoe inserts; painful hallux vagus after 6 month follow up compared to no treatment but may not significantly reduce pain compared to surgery. 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 exists to make decisions regarding prescription of custom orthoses for the treatment of foot pain. There is some evidence of short term reduction of pain in painful pes cavus, foot pain in juvenile idiopathic arthritis, rheumatoid arthritis, plantar fasciitis and hallux valgus.

A Cochrane systematic review (2010) evaluated all randomized and quasi-randomized trials of non-surgical interventions for pediatric pes planus.³⁹ Three trials involving 305 children were included in this review. Due to clinical heterogeneity, data were not pooled. All trials had potential for bias. Data from one trial (40 children with juvenile arthritis and foot pain) indicated that use of custom-made orthoses compared with supportive shoes alone resulted in significantly greater reduction in pain intensity (mean difference (MD) -1.5 points on a 10-point visual analogue scale (VAS), 95% CI -2.8 to -0.2; number need to treat to benefit (NNTB) 3, 95% CI 2 to 23), and reduction in disability (measured using the disability subscale of the Foot Function Index on a 100mm scale (MD -18.65mm, 95% CI -34.42 to -2.68mm). The second trial of seven to 11 year old children with bilateral flat feet (n = 178) found no difference in the number of participants with foot pain between custom-made orthoses, prefabricated orthoses and the control group who received no treatment. A third trial of one to five year olds with bilateral flat feet (n=129) did not report pain at baseline but reported the subjective impression of pain reduction after wearing shoes. No adverse effects were reported in the three trials. The authors concluded that the evidence from randomised controlled trials is currently too limited to draw definitive conclusions about the use of non-surgical interventions for paediatric pes planus. Future high quality trials are warranted in this field. Only limited interventions commonly used in practice have been studied and there is much debate over the treatment of symptomatic and asymptomatic pes planus.

Professional Organizations

The American College of Foot and Ankle Surgery (ACFA) have developed a guideline (2004) for diagnosis and treatment of Pediatric flatfoot.² Pediatric flatfoot is evaluated and designated into a one of the following four categories: flexible flatfoot, rigid flatfoot (subcategorized to: congenital vertical talus, tarsal coalition, peroneal

spastic flatfoot without coalition, or iatrogenic and post traumatic), skew foot, or other etiologies (e.g., neurogenic or muscular abnormalities, genetic syndromes or collagen disorders). Flexible flatfoot is subcategorized into physiological flatfoot where observation is recommended. Nonphysiological flatfoot is subdivided into two categories, asymptomatic or symptomatic. Asymptomatic flatfoot would require observation only. Symptomatic flatfoot would result in treatment options such as activity modification, orthoses, stretching, NSAIDS or modification of comorbid conditions. Foot orthoses are recommended in all of the rigid flatfoot subcategories with the exception of congenital vertical talus where manipulation and serial casting are the recommended treatments.^{2,19} Skew foot are subdivided into symptomatic and asymptomatic categories. No treatment is recommended for asymptomatic skew foot. Symptomatic skew foot is treated based upon age. Manipulation and serial casting are recommended in infants. Orthoses may be recommended but may exacerbate the symptoms in the presence of ankle equines. Other causes of flatfoot are usually associated with generalized ligamentous laxity (e.g., Marfan disease, Ehlers-Danlos, Down's syndrome, cerebral palsy, myelomeningocele, developmental delay, genetic diseases and other syndromes). The ACFA recommend treatment with supportive orthoses for those children with an unstable base of support secondary to flatfoot.

The American College of Foot and Ankle Surgery (ACFA) have developed a guideline (2005) for diagnosis and treatment of Adult Flatfoot.⁸ Adult flatfoot is categorized into the following: non PTTD-adult flatfoot, posterior tibial tendon dysfunction, tarsal coalition, arthritic conditions, post-traumatic, iatrogenic (resulting from over or under correction of many different deformities such as pes cavus, talipes equino varus, pes planovalgus, metatarsus adductus, or achilles tendon lengthening), charcot foot, and other neuromuscular issues. Adult flexible flatfoot (Non-PTTD) is typically a progression of a pediatric condition. The ACFA suggests orthotic management for symptomatic patients. Patients diagnosed with posterior tibial tendon dysfunction are recommended to be treated with conservative treatment options including orthotic management and immobilization, anti-inflammatory medications, physical therapy, patient education and shoe modifications for Stages 1 and 2A or 2B. Stages 3 and 4 require surgical intervention. The ACFA recommends conservative treatment options as the initial treatment for painful tarsal coalition. These options include footwear modifications, arch supports, orthoses, activity modification, appropriate weight reduction, immobilization, and anti-inflammatory medications. Orthotic management and shoe gear modifications are also recommended for iatrogenic/post-traumatic, arthritic adult flatfoot, chronic charcot foot, and neuromuscular flatfoot.

The American Academy of Orthopedic Surgeons (AAOS) on behalf of the American Orthopedic Foot and Ankle Society does not recommend treatment including the use of an orthotic device for painless adult flatfoot. A painful flatfoot may signify an injury to the muscle or tendons of the foot that can progress to problems with walking, climbing stairs and wearing shoes. Conservative treatment using shoe modifications, orthotic devices such as arch supports or orthoses, nonsteroidal anti-inflammatory medications, bracing or casting, physical therapy and rest with ice may be warranted.²⁴ The AAOS position statement on orthotics for adults with pes planus states that "no device needed if there are no symptoms or pain. If there is pain or aching, a semi rigid inserts or long arch pad, inner heel wedge or extended heel counter may help." However, there is no recommendation use of custom orthotics. "No special orthotic device or shoe treatment is indicated for children with pes planus."⁴⁴

CODING INFORMATION

CPT	Description
N/A	

HCPCS	Description
L3000	Foot insert, removable, molded to patient model, UCB type, Berkeley shell, each
L3001	Foot, insert, removable, molded to patient model, Spenco, each
L3002	Foot insert, removable, molded to patient model, Plastazote or equal, each
L3003	Foot insert, removable, molded to patient model, silicone gel, each
L3010	Foot insert, removable, molded to patient model, longitudinal arch support, each
L3020	Foot insert, removable, molded to patient model, longitudinal/metatarsal support, each
L3030	Foot insert, removable, formed to patient foot, each
L3031	Foot, insert/plate, removable, addition to lower extremity orthotic, high strength, lightweight material, all hybrid lamination/prepreg composite, each
L3040	Foot, arch support, removable, premolded, longitudinal, each
L3050	Foot, arch support, removable, premolded, metatarsal, each
L3060	Foot, arch support, removable, premolded, longitudinal/metatarsal, each
L3201	Orthopedic shoe, Oxford with supinator or pronator, infant
L3202	Orthopedic shoe, Oxford with supinator or pronator, child
L3203	Orthopedic shoe, Oxford with supinator or pronator, junior
L3204	Orthopedic shoe, hightop with supinator or pronator, infant
L3206	Orthopedic shoe, hightop with supinator or pronator, child
L3207	Orthopedic shoe, hightop with supinator or pronator, junior
L3212	Benesch boot, pair, infant
L3213	Benesch boot, pair, child
L3214	Benesch boot, pair, junior
L3300	Lift, elevation, heel, tapered to metatarsals, per in
L3310	Lift, elevation, heel and sole, neoprene, per in
L3320	Lift, elevation, heel and sole, cork, per in
L3330	Lift, elevation, metal extension (skate
L3332	Lift, elevation, inside shoe, tapered, up to one-half in
L3334	Lift, elevation, heel, per in

ICD-9	Description (Diagnoses NOT Covered for foot orthotics)
734	Pes planus (acquired)
754.61	Congenital and rigid pes planus

ICD-10	Description (Diagnoses NOT Covered for foot orthotics)
M21.40	Flat foot pes planus acquired unspec foot
M21.41	Flat foot pes planus acquired right foot
M21.42	Flat foot pes planus acquired left foot
Q66.5	Congenital pes planus

RESOURCE REFERENCES

1. U.S. Food and Drug Administration. Code of Federal Regulations Title 21. Limb Orthosis. Accessed at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=890.3475>
2. Harris EJ, Vanore JV, Thomas JL. et al. Clinical Practice Guideline: Diagnosis and treatment of pediatric flatfoot. *The Journal of Foot and Ankle Surgery*. November/December, 2004; 43(6):341-370.
3. Wenger DR, Maudlin D, Speck G, et al. Corrective shoes and inserts as treatment for flexible flatfoot in infants and children. *Journal Bone Joint Surg American* 1989;71(6):800-810.
4. Powell M, Seld M, Szer IS. Efficacy of custom foot orthoses in improving pain and functional status in children with juvenile idiopathic arthritis. *J Rheumatology* 2005; 32(5):943-940.
5. Whitford D, Esterman A. A randomized controlled trial of two types of in-shoe orthoses in children with flexible excess pronation of the feet. *Foot Ankle Int* 2007; 28(6):715-723.
6. Hawke F, Burns J, Radford JA, du Toit V. Custom-made foot orthoses for the treatment of foot pain. *Cochrane Database of Systematic Reviews* 2008, Issue 3. Art. No.: CD006801. DOI: 10.1002/14651858.CD006801.pub2.
7. Hosalkar HS, Spiegel DA, Davidson RS. Kliegman: Nelson Textbook of Pediatrics, 18th ed. Chapter 673-The Foot and Toes. 2007 Saunders. Accessed on April 18, 2010 from MD Consult.
8. Harris EJ, Vanore JV, Thomas JL. et al. Clinical Practice Guideline: Diagnosis and treatment of adult flatfoot. *The Journal of Foot and Ankle Surgery*. March/April 2005;44(2):78-113.
9. Landorf KB, Keenan AM. Efficacy of foot orthoses. What does the literature tell us? *Journal American Podiatry Medical Association* 90(3):149-158, 2000.
10. Staheli LT, Chew DE, Corbett M. The longitudinal arch. A survey of 882 feet in normal children: a report of a screening study. *Journal of Bone and Joint Surgery Am* 1987; 69(3):426-428.
11. El O, Akeali O, Kosay C et al. Flexible flatfoot and related factors in primary schoolchildren: a report of a screening study. *Rheumatology Int* 2006;26(11):1050-1053.
12. Gould N, Moreland M, Alvarez R et al. Development of the child's arch. *Foot Ankle* 1989;9(5):241-245.
13. Garcia-Rodriguez A, Martin-Jimenez F, Carnero-Varo M et al. Flexible flat feet in children: a real problem? *Pediatrics* 1999;103(6):e84.
14. Pfeiffer M, Koyz R, Ledl T et al. Prevalence of flatfeet in preschool-aged children. *Pediatrics* 2006;118(2):634-639.
15. Cowan DN, Jones BH, Robinson JR. Foot morphologic characteristics and risk of exercise-related injury. *Arch Family Medicine* 1993;2(7):773-777.
16. Hogan T, Staheli LT, Arch height and lower limb pain: an adult civilian study. *Foot Ankle Int* 2002;23(1):43-47.
17. Abdel-Fattah MM, Hassanin MM, Felembane FA et al. Flat foot among Saudi Arabian army recruits: prevalence and risk factors. *East Medit Health Journal* 2006;12(1-2):211-217.

18. Harris EJ. The Natural History and Pathophysiology of Flexible Flatfoot. *Clinics in Podiatric Medicine and Surgery*; January 2010;27(1). Accessed from Elsevier MD consult on April 21, 2010.
19. McKie J, Radomisli T. Congenital vertical talus: A review. *Clinical Podiatry Med Surg* 27, 2010:145-156.
20. Canale & Beaty: *Campbell's Operative Orthopedics*, 11th ed. 2007 Mosby. Chapter 79 Pes Planus. Accessed on April 19, 2010 from MD Consult.
21. Johnson K.A., Strom D.E.: Tibialis posterior tendon dysfunction. *Clin Orthop* 1989; 239:196-206.
22. Choi L. DeLee: *DeLee and Drez's Orthopedic Sports Medicine*, 3rd ed. Chapter 14 – Overuse Injuries. 2009 Saunders, Accessed on April 21, 2010 from MD Consult.
23. Chorley J, Powers CR, Hergenroeder AC et al. Clinical features and management of foot pain in the young athlete. In: *UpToDate*, Rose, BD (Ed), UpToDate, Waltham, MA, 2007.
24. American Orthopaedic Foot and Ankle Society on behalf of the American Academy of Orthopedic Surgeons. *Adult (Acquired) Flatfoot*, 2002. Accessed at: <http://orthoinfo.aaos.org/topic.cfm?topic=a00173>
25. Kohls-Gatzoulis J, Angel JC, Singh D et al. Tibialis posterior dysfunction: a common and treatable cause of adult acquired flatfoot.
26. Andorf KB, Keenan AM. Efficacy of foot orthoses. What does the literature tell us? *Journal of American Podiatric Medical Association*. 2000 Mar;90(3):149-58.
27. Murphy A. Canale & Beaty: *Campbell's Operative Orthopedics*, 11 ed. Chapter 79 Pes Planus. Accessed on April 19, 2010 from MD Consult.
28. Chao W, Wapner KL, Lee TH, et al. Nonoperative management of posterior tibial tendon dysfunction. *Foot Ankle Int*. 1996;17(12):736–741
29. Augustyn JF, Lin SS, Berberian WS, Johnson JE. Nonoperative treatment of adult acquired flat foot with the Arizona brace. *Foot Ankle Clin*. 2003;8(3):491–502.
30. Imhauser CW, Abidi NA, Frankel DZ, et al. Biomechanical evaluation of the efficacy of external shoe stabilizers in the conservative treatment of acquired flat foot deformity. *Foot Ankle Int*. 2002;23(8):727–737.
31. Kulig K, Reischl SF, Pomrantz AB et al. Nonsurgical management of posterior tibial tendon dysfunction with orthoses and resistive exercise: a randomized controlled trial. *The Cochrane Central Register of Controlled Trials*. January, 2009;89(1):26-37.
32. Alvarez RG, Marini A, Schmidt C, Saltzman CL. Stage I and II Posterior tibial tendon dysfunction treated by a structured nonoperative management protocol: an orthosis and exercise program.
33. Chao W, Wapner KL, Lee h et al. Nonoperative management of posterior tibial tendon dysfunction. *The Cochrane Central Register of Controlled Trials*. 1999;17(12):736-741.
34. U.S. Department of Health and Human Services. Health Care Financing Administration (HCFA). Prosthetic shoe. Medicare Coverage Issues Manual 70-3. Baltimore, MD HCFA;1999.
35. U.S. Department of Health and Human Services. Health Care Financing Administration (HCFA). Therapeutic shoes for individuals with diabetes. Medicare Coverage Issues Manual 2134. Baltimore, MD HCFA;1999.
36. U.S. Department of Health and Human Services. Health Care Financing Administration (HCFA). Foot Care and supportive devices for the feet. Medicare Coverage Issues Manual 2323. Baltimore, MD HCFA;1999.
37. Document reviewed and Approved by: Advanced Medical Review. Physician reviewer Board certified in Pediatrics, Board certified in Podiatry. April 27, 2010.

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38. Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. Advanced Search: National Coverage Documents [search: orthotic; flatfoot]. Accessed at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>

39. Rome K, Ashford RL, Evans A. Non-surgical interventions for paediatric pes planus. Cochrane Database of Systematic Reviews 2010, Issue 7. Art. No.: CD006311. DOI: 10.1002/14651858.CD006311.pub2
40. Nielsen MD, Dodson EE, Shadrack DL et al. Nonoperative care for the treatment of adult-acquired flatfoot deformity. *J Foot Ankle Surg.* 2011 May-Jun;50(3):311-4. doi: 10.1053/j.jfas.2011.02.002. Epub 2011 Mar 31.
41. Riccio I, Gimigliano F et al. Rehabilitative treatment in flexible flatfoot: a perspective cohort study. *Chir Organi Mov.* 2009 Dec;93(3):101-7. doi: 10.1007/s12306-009-0037-z. Epub 2009 Sep 24.
42. Jung DY, Koh EK, Kwon OY. Effect of foot orthoses and short-foot exercise on the cross-sectional area of the abductor hallucis muscle in subjects with pes planus: a randomized controlled trial. *J Back Musculoskelet Rehabil* - 2011; 24(4); 225-31.
43. Jane Mackenzie A, Rome K, Evans AM. The efficacy of nonsurgical interventions for pediatric flexible flat foot: a critical review. *J Pediatr Orthop* - Dec 2012; 32(8); 830-4
44. American Academy of Orthopedic Surgeons Position Statement for Orthotics and Pes Planus. Accessed at: <http://orthoinfo.aaos.org/topic.cfm?topic=a00172>
45. Advanced Medical Review (AMR): Policy reviewed and approved by MD board certified in Orthopedics, 4/2/13.