Clinical Indications

- **Foot orthotics** are considered medically necessary for patients who meet **ALL** of the following selection criteria:
  - Patient has **1 or more** of the following conditions:
    - Adults (skeletally mature feet) [A]:
      - Acute or chronic plantar fasciitis
      - Acute sport-related injuries (including: diagnoses related to inflammatory problems; e.g., bursitis, tendonitis)
      - Calcaneal bursitis (acute or chronic)
      - Calcaneal spurs (heel spurs)
      - Conditions related to diabetes (see section above on therapeutic shoes for diabetes for a complete list of medically necessary diagnoses)
      - Inflammatory conditions (i.e., sesamoiditis; submetatarsal bursitis; synovitis; tenosynovitis; synovial cyst; osteomyelitis; and plantar fascial fibromatosis)
      - Medial osteoarthritis of the knee (lateral wedge insoles)
      - Musculoskeletal/arthropathic deformities (including: deformities of the joint or skeleton that impairs walking in a normal shoe; e.g., bunions, hallux valgus, talipes deformities, pes deformities, anomalies of toes)
      - Neurologically impaired feet (including: neuroma; tarsal tunnel syndrome; ganglionic cyst; and neuropathies involving the feet, including those associated with peripheral vascular disease, diabetes, carcinoma, drugs, toxins, and chronic renal disease)
      - Vascular conditions (including: ulceration, poor circulation, peripheral vascular disease, Buerger's disease (thromboangiitis obliterans), chronic thrombophlebitis).
    - Children (skeletally immature feet):
      - Hallux valgus deformities
      - In-toe or out-toe gait
      - Musculoskeletal weakness (e.g., pronation, pes planus)
      - Structural deformities (e.g., tarsal coalitions)
      - Torsional conditions (e.g., metatarsus adductus, tibial torsion, femoral torsion)
• The patient must have symptoms associated with the particular foot condition (foot orthotics are not considered medically necessary when the foot condition does not cause symptoms)

• The patient has failed to respond to a course of appropriate conservative treatment (e.g., physical therapy, injections, strapping, anti-inflammatory medications).
  Orthotics should not be considered first line therapy.

• 1 or more of the following types of foot orthotics are considered medically necessary for the above listed indications:
  ▪ **Shoe modifications** to standard non-orthopedic shoes, e.g., rocker soles, shoe buildups, metatarsal bars, shoe stretching, Thomas heels, tongue pds, velcro closures, modified lacers, etc., may be considered medically necessary to compensate for minor foot deformities. Shoe modifications are medically prescribed alternants to shoes to accommodate minor foot deformities, disabilities, or leg shortening of less than 1.5 inches
  ▪ **Over-the-counter standard orthopedic Oxford shoes** are considered medically necessary when the foot can reasonably be accommodated in this type of shoe. A standard orthopedic Oxford is a prefabricated shoe that can accommodate an inlay.
  ▪ **Inlay shoes** are considered medically necessary when shoe modifications will not accommodate the foot deformity and that an insole or additional space is needed. Depth inlay shoes are pre-fabricated shoes with a higher toe box to accommodate for hammer toes and other foot deformities. These shoes are usually made of plastizote or other pressure absorbing material. Medically necessary depth inlay shoes (depth shoes) should meet criteria set forth in section above on therapeutic shoes for diabetes.
  ▪ **Healing or cast shoes** are considered medically necessary when the foot can not be slipped into a standard shoe. Replacement or repair of healing or cast shoes is usually not medically necessary since this shoe is normally needed for a short period of time. Spare plastizole healing shoes are not considered medically necessary since these shoes are used for a short duration.
  ▪ **Molded shoes** are considered medically necessary if no other type or shoe or modification adequately accommodates the foot deformity of condition.
  ▪ **Custom made orthopedic shoes** are considered medically necessary when the members needs can not be accommodated by other foot orthotics. Custom-made orthopedic shoes are considered medically necessary when the severity of the foot condition is such that a lesser means, for example, inlay shoes, shoe modifications, etc., can not adequately compensate for the deformity or there is a leg discrepancy length of at least 1.5 inches or greater. Custom-made orthopedic shoes are shoes fabricated over special modified lasts in accordance with
prescriptions and specifications to accommodate gross or greater foot deformities or shortening of a leg of 1.5 inches or greater. A last is a form which is shaped like a human foot over which a shoe is manufactured or repaired. The severity of the foot deformity requires the physical presence of the member for casts, measurements, and trial fittings.

- **Modifications of custom made/molded, and depth shoes**: An individual may substitute modifications of custom made/molded or depth shoes instead of obtaining a pair of inserts in any combination. (Note: Payment for the modifications may not exceed the limit set for the inserts for which the individual is entitled). See section on therapeutic shoes for diabetes for description of modifications to custom-molded and depth shoes.

  - **Diabetic Therapeutic shoes**[^1] (depth or custom-molded) along with inserts are considered medically necessary for patients with diabetes mellitus and meets **ALL** of the following
    - Member has **1 or more** of the following conditions
      - Foot deformity
      - History of pre-ulcerative calluses
      - History of previous ulceration
      - Peripheral neuropathy with evidence of callus formation
      - Poor circulation
      - Previous amputation of the foot or part of the foot
    - **1 or more** of the following items are considered medically necessary for persons with diabetes who meet the criteria for diabetic shoes listed above:
      - Depth shoes with the following characteristics[^2] are considered medically necessary when **ALL** of the following are met:
        - Are available in full and half sizes with a minimum of 3 widths so that the sole is graded to the size and width of the upper portions of the shoes according to the American standard sizing schedule or its equivalent. (The American standard last sizing schedule is the numerical shoe sizing system used for shoes sold in the United States)
        - Are made of leather or other suitable material of equal quality
        - Have a full-length, heel-to-toe filler that, when removed, provides a minimum of 3/16th inch of additional depth used to accommodate custom-molded or customized inserts
        - Have some sort of shoe closure
    - **Custom-molded shoes** with **ALL** of the following characteristics[^3] are considered medically necessary when the member has a foot deformity that can not be accommodated by a depth shoe:
      - Constructed over a positive model of the member's foot
• Have removable inserts that can be altered or replaced as the member's condition warrants
• Have some sort of shoe closure
• Made from leather or other suitable material of equal quality

**Modifications of custom-molded and depth shoes**[^E] An individual may substitute modifications of custom-molded or depth shoes instead of obtaining a pair of inserts in any combination. Any 1 or more of the following is a list of the most common shoe modifications available, but it is not meant as an exhaustive list of the modifications available for diabetic shoes:

- **Inserts:** Medically necessary inserts are those that are total contact, multiple densities, removable inlays that are directly molded to the member's foot or a model of the member's foot and are made of a material suitable for the member's condition.
- **Metatarsal bars:** These are exterior bars that are placed behind the metatarsal heads in order to remove pressure from the metatarsal heads. The bars are of various shapes, heights, and construction depending on the exact purpose.
- **Offset heels:** This is a heel flanged at is base either in the middle, to the side, or a combination, that is then extended upward to the shoe in order to stabilize extreme positions of the hind foot.
- **Rigid rocker bottoms:** These are exterior elevations with apex positions for 51% to 75% distance measured from the back end of the heel. The apex is a narrowed or pointed end of an anatomical structure. The apex must be positioned behind the metatarsal heads and tapering off sharply to the front tip of the sole. Apex height helps to eliminate pressure at the metatarsal heads. The steel in the shoe ensures rigidity. The heel of the shoe tapers off in the back in order to cause the heel to strike in the middle of the heel.
- **Roller bottoms (sole or bar):** These are the same as rocker bottoms, but the heel is tapered from the apex to the front tip of the sole.
- **Wedges (posting):** Wedges are either of hind foot, fore foot, or both and may be in the middle or to the side. The function is to shift or transfer weight upon standing or during ambulation to the opposite side for added support, stabilization, equalized weight distribution, or balance.

**Other medically necessary modifications** to diabetic shoes include, but are not limited to 1 or more of the following:

- Flared heels
- Inserts for missing toes
- Velcro closures

**A prosthetic shoe** is a device used when all or a substantial portion of the front part of the foot is missing.[^F] A prosthetic shoe can be considered as a terminal device; i.e., a structural supplement replacing a totally or substantially absent hand or foot. Terminal
devices such as hooks and prosthetic shoes may be considered prosthetics in place of an artificial hand or foot. **1 or more** of the following per member per calendar year is considered medically necessary:

- No more than 1 pair of custom-molded shoes (including inserts provided with the shoes) and 2 additional pairs of inserts
- No more than 1 pair of depth shoes and 3 pairs of inserts (not including the non-customized removable inserts provided with such shoes).

**Shoe modifications and replacements:** Medical necessity criteria for replacements of or modifications to existing customized shoes is based on the same criteria noted for the shoe itself. Replacement of a pair of shoes, or modifications, should be based on necessity (e.g., worn out, loss of effectiveness), not for convenience or style change. Due to wear and tear with normal use, orthotics may need refurbishing periodically, every 1 or 2 years. Replacement of orthotics is generally not necessary more often than every 2 years.

**Indications considered Not Medically Necessary**

- **1 or more** of the following indications are considered not medically necessary:
  - Orthotic devices made on the same date as an open cutting surgical procedure (e.g., bunionectomy) are not considered medically necessary. Only 1 orthotic per foot is considered medically necessary. Separate orthotics for each pair of patient's shoes are not considered medically necessary.
  - Foot orthotics have no proven value for back pain, knee pain (other than medial osteoarthritis), pes planus (flat feet), pronation, corns and calluses, hammertoes, hip osteoarthritis, and lower leg injuries.
  - Therapeutic shoes and inserts for diabetes are considered experimental and investigational when these criteria are not met. These criteria are consistent with the Centers for Medicare and Medicaid Services (CMS) guidelines.
  - Over-the-counter orthotics are considered medically necessary for short-term use (e.g., for a few weeks to a couple of months) for acute conditions. They are not considered medically necessary if used to replace custom made orthotics that are for chronic, long-term use, as they would need to be replaced frequently. Over-the-counter orthotics are not appropriate for children.
  - Spinal Pelvic Stabilizers (Foot Levelers, Inc.) are specialized custom molded inserts designed to prevent foot injuries and improve foot alignment; these are considered investigational because their value in treatment of foot disease has not been proven.

**Evidence Summary**
Inappropriate Indications

- CONDITIONS LISTED AS NOT MEDICALLY NECESSARY OR INVESTIGATIONAL
- The following conditions or uses of custom foot orthotics are considered investigational or not medically necessary:
  - Hammer Toe
  - Pes Planus
  - Pronation
  - Corns and Calluses
  - Knee Pain
  - Back Pain
  - For use during sports or athletic performances

Background

- The terms used to describe orthotics were very confusing: often, clinicians used different terms to describe even the most basic device. Devices or parts of orthoses were given names that might describe their purpose, the body part to which they were applied, the inventor of the device, or where they were developed.
- To minimize confusion, a system of standard terminology has been developed. The system uses the first letter of each joint that the orthosis crosses in correct sequence, with the letter "O" for orthosis at the end. Thus, the more common orthoses would be named AFO (ankle-foot orthosis), KAFO (knee-ankle-foot orthosis), and KO (knee orthosis). A properly written orthotic prescription does not just state the name of the orthosis; it also is necessary to state the desired function to be obtained, the specific material from which the device is to be made, and the specific design and construction that is to be employed.
- Accommodative foot orthoses are custom or non-custom inlays fabricated for the purpose of providing relief from callosities and pressure points, and maintaining the integrity of the longitudinal arch and/or the metatarsal heads.
- Functional foot orthoses are foot plates fabricated from plaster molds of the feet or electronic (computer) imaging in a semi-weight bearing or non-weight bearing, neutral position, with corrections built in to prevent abnormal compensation during the gait cycle.
- Custom-made orthopedic shoes are shoes fabricated over special modified lasts in accordance with prescriptions and specifications to accommodate gross or greater foot deformities or shortening of a leg at least 1 and 1/2 inches or greater. Custom-made
orthopedic shoes may be necessary when a physician or podiatrist determines that the severity of the foot condition is such that a lesser means, for example, inlay shoes, shoe modifications, etc., cannot adequately compensate for the deformity or there is a leg discrepancy length at least of 1 and 1/2 inches in length or greater. Initial custom-made orthopedic shoes, lasts, and patterns normally are obtained when the severity of the foot disability requires the physical presence of the member for casts, measurements, and possible trial fittings.

- A shoe modification is a medically prescribed alteration(s) to a shoe(s) to accommodate minor foot deformities, disabilities, or leg shortening of less than 1 and &frac12; inches. Shoe modifications, e.g., rocker soles, shoe buildups, metatarsal bars, shoe stretching, Thomas heels, tongue pads, velcro closures, modified lacers, etc., may be applied to personally purchased shoes, upon medical determination of need, to compensate for minor foot deformities.

- Depth inlay shoes are prefabricated shoes with a higher toe box to accommodate for hammer toes and other deformities. This shoe may also accommodate the insertion of special inserts. These shoes are traditionally made of plastizote or other pressure absorbent material. Inlay shoes may be necessary after it has been determined that shoe modifications will not accommodate the foot deformity and that an insole or additional space is necessary.

- Healing shoes are prefabricated shoes with a higher toe box to accommodate for hammer toes and other deformities. This shoe may also accommodate the insertion of special inserts. Healing and/or cast shoes may be necessary when the foot cannot be slipped into a standard shoe.

- Patterns are cardboard tracing (templates) comprising the shoe's upper and innersole components.

- A last is a form which is shaped like the human foot over which a shoe is manufactured or repaired.

- A standard orthopedic Oxford is a prefabricated shoe that can accommodate an inlay, e.g., dress, casual, and athletic shoes. Over the counter (OTC) standard orthopedic Oxford (dress, casual, athletic) should be used when a foot can be reasonably accommodated in this type of shoe.

- Orthotic shoes or orthopedic shoes: special shoes for certain unusual or abnormal foot conditions, to improve comfort and function. They are created mostly for recreational use and for pathologic foot conditions. This definition includes high-quarter shoes, or chukka boots, which cover the medial malleoli.

- Reese Orthopedic Shoe is a canvas and wooden sole shoe used post-operatively to reduce motion in joints of the foot. This shoe is also known as a Darby Shoe.

- Clawson Rocker Shoes serve as a walking aid for patients with multiple sclerosis.

- Straight Last shoes serve as a corrective splint for metatarsus adductus.
• **Modifications of stock shoes:** Shoe modifications can be classified as internal (i.e., those that are inserted into the inner surface of the shoe or sandwiched between shoe components) or external (i.e., those that are attached to the sole or heel).

• **Internal shoe modifications:** inner shoe corrections include steel shanks, cookies (i.e., scaphoid and metatarsal pads), interior heel lifts and wedges, extended or reinforced heel counters, and protective metal toe boxes.

• Steel shanks: used to support a weak longitudinal arch.

• Cookies: includes scaphoid and metatarsal pads. Made of firm materials such as leather or rubber, can also be used to support a weak longitudinal arch.

• Scaphoid pads: also used to provide additional longitudinal arch support, but are made of compressible material, and are prescribed for people who cannot tolerate the firmness of a cookie.

• Long medial counters: made of firm material, such as rigid leather, the insertion of a long medial counter can improve the longitudinal arch support of a cookie or scaphoid pad.

• Metatarsal pads: available commercially, the metatarsal pads may be positioned inside the shoe just proximally to the metatarsal heads to protect and reduce pressure on the second, third, and fourth metatarsal heads.

• Sesamoid (also known as a dancer’s pad): is thicker and broader than a metatarsal pad, and extends medially to the proximal part of the first metatarsal head. Thus, it provides greater support for more severe cases of metatarsalgia.

• Interior heel wedges: range in size from 0.0625 to 0.125 inch in height, and can be placed on either one-half of the interior heel.

• Arch supports: are orthotic devices that are individually molded for specific patient needs (i.e. torsional conditions, structural deformities, calcaneal spurs).

• **External shoe modifications:** External shoe modifications include sole and heel wedges, flanges and elevations, metatarsal and rocker bars, and different types of heel designs.

• Wedges: are constructed of leather and positioned under the outer sole or heel. Sole and heel wedges usually are placed medially but occasionally they are laterally placed to shift the body weight from that side of the foot to the other.

• Shoe Wedge is any device, generally constructed of leather that is placed on the side of the walking surface of a shoe or within the shoe construction itself, and not in direct contact with the foot. The purpose of a shoe wedge is to redistribute the flow of weight through the foot.

• 1st Metatarsal Head is a wedge that extends on the medial side of the shoe from the breast of the heel to the 1st metatarsal head.

• Full Lateral is a wedge on the outer side of the shoe; extending from the heel to the tip of the shoe.
• Full Medial is a wedge on the medial (inner) side of the shoe, extending from the heel to the tip of the shoe.
• Lateral Dutchman is a wedge that is placed on the lateral (outside) margin of the sole of the shoe.
• Medial Dutchman is a wedge that is placed on the medial (inner) side of the sole of the shoe.
• Medial Tip is a wedge placed on the medial (inner) side of the tip of the sole of the shoe.
• Flanges or flare outs: are 0.25-inch wide medial or lateral extensions of the sole or heel that provide rotatory stability. A lateral flange provides a lever-arm, which ensures a foot flat in the presence of excessive inversion or varus deformity. Such small lateral flanges are seen on most commercially available runner's shoes.
• Elevations (i.e., lifts): elevations of the sole or heel are prescribed for leg length discrepancies. Elevations of greater than 0.25 inches are placed externally.
• Bars: are a build-up on the exterior of the sole of the shoe (usually made of leather or rubber) to control distribution of weight to the foot.
• Metatarsal bar: made of leather or rubber, and may be attached transversely to the outer sole immediately proximal to the metatarsal heads to relieve pressure on them and to reduce pain.
• Kidney is a kidney-shaped metatarsal bar.
• Rocker bar: placed similarly to the metatarsal bar, but extends distally beyond the metatarsal heads. It relieves pressure on the metatarsal heads, and also reduces metatarsal phalangeal flexion on push-off by providing a smooth plantar roll to toe-off.
• Denver bar: placed under the metatarsal bones to support the transverse arch extending from the metatarsal heads anteriorly to the tarsal metatarsal joints posteriorly.
• Anterior heel is a bar that is effective in providing a broad distribution of weight. The device consists of a leather raise extending from the front part of the shank where it meets the sole backward to half the distance of the shank.
• Comma is a bar put on a shoe behind the metatarsal heads; it has the shape of a comma. The posterior and lateral side of the bar is thicker and is positioned under the middle of the shank of the shoe.
• Mayo is a bar cemented to the sole of the shoe proximal to the forefoot treading surface.
• Thomas is a metatarsal bar "190; wide by 2/8" - 3/8" thick; the bar is skived thin at the posterior end and applied on the exterior of the sole of the shoe behind the metatarsal heads. This provides for the relief of pressure off of the metatarsal heads.

External heel modifications:
• See heel elevations, wedges, and flanges under internal shoe modifications.
• The heel of a shoe may vary in size, shape, height and construction.
• The Thomas heel or the orthopedic heel is similar in design and material to the regular flat heel but has an anteriomedial extension to provide additional longitudinal arch
support. This extension may be of variable length, depending on the extent of the support required, and its effect may be augmented further by a medial wedge or a Thomas heel wedge.

- Reverse Thomas heel: an anterolateral extension to support a weak lateral longitudinal arch.
- Heel cushion (such as the solid ankle cushion (SACH) heel): made of compressible resilient materials, usually in conjunction with a rocker bar for cushioning effect on heel strike.
- Extended: is a heel with an anterior extension on the medial side.
- Flared: is a heel flared on either the medial, lateral, or posterior sides, or any combination of sides, allowing for a wider base to the heel to control the distribution of body weight to the foot and its gravitational center.
- Wedge: is a wedge of leather or other material added as an exterior or interior modification at the heel; to assist in balance or stabilization of the foot. See section on wedges above.

**Splints (mechanical bars):**

- Splints are mechanical devices applied to special shoes, comprised of an attachment of a stationary or movable adjustable bar between the shoes to control the position and the motion of the feet while standing and walking for the purpose of correcting foot deformities.
- Brachman Splint is a movable bar attached to the shoes that permits reciprocal motion of the feet.
- Dennis-Brown Bar is a non-movable or stationary bar attached to the shoes.
- Filauer Bar is similar to a Dennis-Brown bar; the difference is that it has an adjustment that allows for an internal or external rotational position of the foot.
- Friedman Bar is a leather rectangular bar that is attached to the back of the heels of the shoes to control in-toeing or out-toeing.
- Gottler Splint is a device applied to a special shoe to prevent the forefoot from in-toeing (adducting).
- Night Splint is an established therapeutic option for plantar fasciitis.

**Plates:** Plates are rigid type foot orthotics used for correction, stabilization and gait training of the foot.

- Whitman's is a rigid appliance, made of stainless steel or plastic that acts as an action brace. The appliance has a medial flange and lateral clip; no heel seat. It extends distally to the first metatarsal head only and then laterally to the base of the fifth metatarsal.
- Reverse Whitman's are the same as Whitman's; the difference is that an extension of metal or plastic goes to the fifth metatarsal head, instead of the first metatarsal head.
• Robert's is a rigid appliance, usually metal or plastic, with a medial flange and lateral clip and heel seat. The plate extends distally to all metatarsal heads. Shaeffer is a custom-made rigid orthotic to stabilize the foot.

• **Foot orthoses:** Orthotics are mechanical devices which are placed in a shoe (shoe inserts) to assist in restoring or maintaining normal alignment of the foot, relieve stress from strained or injured soft tissues, bony prominences, deformed bones and joints, and inflamed or chronic bursae (e.g., arch supports). Removable foot supports are placed inside the shoe to manage different foot symptoms and deformities. The devices can be made of several different types of materials and are usually designed to the measurement, plaster models and patterns of the foot and leg. They may be available commercially or may be custom-made. The usual indications for foot orthoses are to relieve pressure on areas that are painful, ulcerated, scarred, or callused, to support weak or flat longitudinal or transverse foot arches, and to control foot positions and thus affect the alignment of other lower limb joints. All are concerned with improving foot function, controlling foot motion, reducing shock absorption and minimizing stress forces that could ultimately cause foot deformity and pain.

• Soft or flexible foot orthoses are made from soft compressible materials, such as leather, cork, rubber, soft plastics, or plastic foam (Spenco, PPT, Pelite). Many of these are commercially available and used for simple problems. Soft orthotics help to absorb shock, increase balance, and take pressure off uncomfortable or sore spots. Soft foot orthoses are worn against the sole of the foot and are usually fabricated in full length from heel to toe with increased thickness where weight bearing is indicated and relief where no or little pressure should occur. Plastic foam orthoses are available in different density and thickness and are commonly used for ischemic, insensitive, ulcerated, and arthritic feet. The advantage of any soft orthotic is that it may be easily adjusted to changing weight-bearing forces. The disadvantage is that it must be replaced more often than rigid orthotics. A soft orthotic is particularly effective for diabetes, the arthritides and for grossly deformed feet where there is the loss of protective fatty tissue on the side of the foot. Soft orthotics are also widely used in the care of healing ulcers in the insensitive foot.

• Semi-rigid and rigid orthoses come in a variety of materials such as leather, cork, and metals, but most commonly they are made of solid plastics, which allow minimal flexibility. These orthoses generally extend from the posterior end of the heel to the metatarsal heads (i.e., three-quarter length), and may have medial or lateral flanges. They are molded to provide support under the longitudinal arch and metatarsal area and to provide relief for painful or irritated areas. The most rigid foot orthoses (e.g., Whitman, Mayer, and Shaffer plates; Boston arch supports) are made of metal, usually steel or duralumin, and are covered with leather.
Rigid orthotics are designed to control function. They are made of a firm material such as plastic, leather, fiberglass or acrylic polymer. The finished device normally extends along the sole of the heel to the ball or toes of the foot. It is worn mostly in closed shoes with a heel height under two inches. Rigid orthotics are chiefly designed to control motion in two major foot joints, which lie directly below the ankle joint. These devices are long-lasting, do not change shape, and are usually unbreakable. Strains, aches, and pains in the legs, thighs, and lower back may be due to abnormal function of the foot or a slight difference in the length of the legs. In such cases, orthoses may improve or eliminate these symptoms which at first may seem only remotely connected to foot function. Molded polypropylene orthoses (foot/ankle/leg) are used to manage spastic and flaccid paralysis due to neurodeformities (e.g., cerebral palsy).

Semi-rigid orthotics provide for dynamic balance of the foot while walking or participating in sports. Each sport has its own demand and each orthotic needs to be constructed appropriately with the sport and the athlete taken into consideration. The functional dynamic orthotic helps guide the foot through proper functions, allowing the muscles and tendons to perform more efficiently. The classic, semi-rigid orthotics constructed using laminations of leather and cork, reinforced by a material called Silastic. It may also be made of polymer composites.

Strappings, paddings, and appliances may be applied directly to the foot and toes to correct deformities and protect tender areas such as corns, calluses, ulcers, nails, and bony outgrowths from excessive friction or pressure.

Gélis et al (2008) developed clinical practice guidelines for the use of foot orthoses (FO) in the treatment of knee and hip osteoarthritis (OA). The French Physical Medicine and Rehabilitation Society's methodology, associating a systematic review of the literature, input from everyday clinical practice and external review by a multi-disciplinary expert committee, was employed. The selected analysis criteria were pain, disability, medications used as well as X-ray evolution of OA. Recommendations were classified according to the level of proof in grade A, B or C according to the French National Agency for Health Accreditation and Evaluation. In medial knee OA, foot pronation orthotics -- when there are no contraindications -- can be proposed for their symptomatic impact, especially in the decrease of non-steroidal anti-inflammatory drugs consumption (grade B). To this day, there is no evidence of a structural or functional impact on OA (grade B). Outside of this specific clinical framework, there is no validated indication for prescribing FO in the treatment of knee or hip OA (grade C). The authors concluded that it is necessary to have further randomized controlled trials to better define the indication of FO (severity of knee OA, genuvarum), test the efficacy of other orthoses such as cushioning FO. The long-term side effects, mainly on the external femoro-tibial compartment could also be assessed. A medical and economical assessment of FO prescriptions is also quite necessary.
• Hume and associates (2008) reviewed the effectiveness of FO for treatment and prevention of lower limb injuries. Qualifying studies were mainly controlled trials, but some uncontrolled clinical trials of patients with chronic injuries were analyzed separately. Injuries included plantar fasciitis, tibial stress fractures and patello-femoral pain syndrome; these were included because of the large treatment costs for these frequent injuries in New Zealand. Outcomes were pain, comfort, function and injury status. Continuous measures were expressed as standardized differences using baseline between-subject standard deviations, and magnitudes were inferred from the intersection of 90% confidence intervals (CIs) with thresholds of a modified Cohen scale.Effects based on frequencies were expressed as hazard ratios and their magnitudes were inferred from intersection of CIs with a novel scale of thresholds. The effects of FO for treatment of pain or injury prevention were mostly trivial. Foot orthoses were not effective in treating or preventing patello-femoral pain syndrome. Some studies showed moderate effects for treatment of plantar fasciitis. Only a few studies showed moderate or large beneficial effects of FO in preventing injuries. Customized semi-rigid FO have moderate to large beneficial effects in treating and preventing plantar fasciitis and posterior tibial stress fractures, and small to moderate effects in treating patello-femoral pain syndrome. Given the limited randomized controlled trials (RCTs) or clinical controlled trials available for the injuries of interest, it may be that more or less benefit can be derived from the use of FO, but many studies did not provide enough information for the standardized effect sizes to be calculated. The authors stated that further research with RCTs is needed to establish the clinical utility of a variety of FO for the treatment and prevention of various lower limb injuries. In this regard, Vicenzino et al (2008) reported that a single-blinded RCT will be conducted to investigate the clinical efficacy and cost effectiveness of FO in the management of patello-femoral pain syndrome.

• **Ankle-foot orthoses:** Ankle-foot orthoses are most commonly prescribed for muscle weakness affecting the ankle and subtalar joints, such as weakness of the dorsi and plantar flexors, invertors, and evertors. Ankle-foot orthoses can also be prescribed for prevention or correction of deformities of the foot and ankle and reduction of weight-bearing forces. In addition to having mechanical effects on the ankle, the AFOs may affect the stability of the knee by varying the degree of plantar or dorsiflexion at the ankle. An ankle fixed in dorsiflexion will provide a flexion force at the knee and thus may help to prevent genu recurvatum; a fixed plantarflexion will provide an extension force that may help to support a weak knee during the stance phase of gait. Although traditional metal orthoses still are prescribed, plastic ankle-foot orthoses are more common. Inexpensive, ready to use AFOs are widely available and useful for minor or temporary deficits, but custom-made orthoses are indicated for more severe and permanent deficits. Plastic AFOs are worn inside the shoe and consist of the footplate, an upright component, and a Velcro calf strap. The upright components on plastic AFOs...
vary in design, depending on the desired function, but usually these extend from the footplate without a joint mechanism to the upper calf approximately 1 to 2 inches below the head of the fibula.

- Metal AFOs usually have both medial and lateral uprights with an ankle joint mechanism. The uprights are attached to the shoe by a stirrup and secured to the calf by a padded leather-covered calf band, leather strap, and a buckle. Sturdy shoes, such as orthopedic shoes, are required for metal orthoses. The stirrups usually are attached directly to the shoe between the sole and heel, although the footplate inside the shoe occasionally is used. The upper end of the stirrups connects with the uprights at the ankle joint. The solid stirrup is used most commonly and provides the most rigid and least bulky shoe attachment. The split stirrup allows transfer of the orthosis to any shoe with a flat caliper insertion. Knee-ankle-foot orthoses: Knee-ankle-foot orthoses are prescribed to provide knee stability for weight bearing in the presence of severe lower limb weakness due to upper or lower motor neuron disease.

- Figueiredo et al (2008) performed a literature review evaluating the quality of current research on the influence of AFOs on gait in children with cerebral palsy (CP). Two between-group and 18 within-group studies met the inclusion criteria indicating a low level of evidence. Between-group studies each scored "4" on the PEDro Scale, and 17 within-group studies scored "3" and 1 scored "2", indicating low quality. Standard terminology for AFOs was not used and only 6 studies described functional status using appropriate instruments. The authors concluded that studies using high quality methods are still needed to support evidence-based decisions regarding the use of AFOs for this population.

- **Hip-knee-ankle-foot orthoses:** Hip-knee-ankle-foot orthoses consist of the same components as described for the standard AFOs and KAFOs, with the addition of an attached lockable hip joint and a pelvic band to control movements at the anatomic hip joint.

- **Fracture orthoses:** These include rigid, plaster-of-Paris casts which are applied to a fractured limb to provide rigid immobilization while healing occurs, to fracture orthoses that permits mobilization of joints adjacent to the fracture. These latter types of fracture orthoses have been used most often to treat fractures of the shafts of the tibia and femur when internal fixation is unnecessary, contraindicated, or refused by the patient, and when healing is significantly delayed or does not occur. They allow functional ambulation with progressively increasing weight bearing. The fracture orthoses include three main components: a cylinder that fits closely to the fractured limb; a footplate, which is worn inside the shoe; and a joint mechanism, which attaches the footplate to the cylindrical component. Similar joint mechanisms may be used for the knee, connecting the above- and below-knee pieces.
Latex Shield is a protective shield made to the plaster model of a patient's toe or part of the foot. The materials used are latex, rubber paddings and nylon or chamois. It is used to protect a deformity from pressure.

**Lateral wedge insoles for knee osteoarthritis:**

In a randomized study, Toda and Tsukimura (2006) evaluated the effect of wearing a lateral wedged insole with a subtalar strap for 2 years in patients with osteoarthritis varus deformity of the knee (knee OA). A total of 61 female outpatients with knee OA who completed a prior 6-month study were asked to wear their respective insoles continuously as treatment during the course of the 2-year study. The femoro-tibial angle (FTA) was assessed by standing radiographs obtained while the subjects were barefoot and the Lequesne index of the knee OA at 2 years was compared with those at baseline in each insole group. A total of 13 patients (21.3 %) did not want to wear the insole continuously and 5 (8.2 %) withdrew for other reasons. The 42 remaining patients who completed the 2-year study were evaluated. At the 2-year assessment, participants wearing the subtalar strapped insole (n = 21) demonstrated significantly decreased FTA (p = 0.015), and significantly improved Lequesne index (p = 0.031) in comparison with their baseline assessments. These significant differences were not found in the group with the traditional shoe inserted wedged insole (n = 21). The authors concluded that only those subjects using the subtalar strapped insole demonstrated significant change in the FTA in comparison with the baseline assessments. If the insole with a subtalar strap maintains FTA for more than 2 years, it may restrict the progression of degenerative articular cartilage lesions of knee OA.

Shimada et al (2006) examined the effects of lateral wedged insoles on knee kinetics and kinematics during walking, according to radiographic severity of medial compartment knee OA. A total of 46 medial compartment knees with OA of 23 patients with bilateral disease and 38 knees of 19 age-matched healthy subjects as controls were included in this study. These investigators measured the peak external adduction moment at the knee during the stance phase of gait and the first acceleration peak after heel strike at the lateral side of the femoral condyles. Kellgren and Lawrence grading system was used for radiographical assessment of OA severity. The mean value of peak external adduction moment of the knee was higher in OA knees than the control. Application of lateral wedged insoles significantly reduced the peak external adduction moment in Kellgren-Lawrence grades I and II knee OA patients. The first acceleration peak value after heel strike in these patients was relatively high compared with the control. Application of lateral wedged insoles significantly reduced the first acceleration peak in Kellgren-Lawrence grades I and II knee OA patients. The authors concluded that the kinetic and kinematic effects of wearing of lateral wedged insoles were significant in Kellgren-Lawrence grades I and II knee OA. The results support the
recommendation of use of lateral wedged insoles for patients with early and mild knee OA.

- Kuroyanagi et al. (2007) compared the use of two lateral wedged insoles (one with, and the other without subtalar strapping) in patients with medial knee OA. A total of 21 patients (aged 58 to 83 years, mean 70 of 2) with medial knee OA were enrolled. Thirty-seven knees in the patients were divided into three groups based on the Kellgren and Lawrence OA grading system; grades 2 (n = 20), 3 (n = 11), and 4 (n = 6). Subjects were tested during walking barefoot and during walking with a silicon rubber lateral wedged insole with elevation of 10 mm attached to a barefoot. Gait analysis was performed on a 10-m walkway for each subject under three different walking conditions: (i) barefoot, (ii) wearing a conventional insole, and (iii) a subtalar strapping insole. Peak knee varus moment during gait was measured under each condition, and compared between the three conditions and between the OA grades. On the whole (n = 37), the peak varus moment was significantly reduced by wearing either of the insoles, compared to walking barefoot. The reduction was more obvious with the strapping insole (-13 %, p < 0.01), compared with the conventional insole (-8 %, p < 0.05). In moderate OA patients (grades 2 and 3), the moments were significantly lower with the strapping insole, compared with the conventional insole (p = 0.0048 and 0.005, respectively). However, no significant difference was detected in severe OA patients (grade 4) between the two types of insoles (p = 0.4). The authors concluded that both lateral wedged insoles significantly reduced the peak medial compartment load during gait. The subtalar strapping insole had a greater effect than the conventional insole, particularly in patients with moderate medial knee OA.

- A guideline on OA of the knee published by the Singapore Ministry of Health (2007) stated that lateral wedge insoles (tilt angle of 8.5 to 11 degrees) should be used to provide pain relief for patients with OA of the knee with medial OA symptoms.

References


Appendix

Pathology
Forefoot deformities: Hallux abducto valgus, hallux varus, hallux rigidus

Shoe Type
Stock Shoes* Oxford style boot** Depth shoes Custom molded shoes

Insert Modification (as needed)
Semi-rigid or rigid functional orthosis, Additional accommodative padding as needed

Comments
Semi-rigid or rigid functional orthosis, Additional accommodative padding as needed, Ankle-foot orthosis or other stabilization and/or immobilization brace

**Comments**
The type of shoe and orthotic must be determined based on the severity of the pathology.

**Pathology**
Midfoot deformities: Charcot foot

**Shoe Type**
Depth shoe Custom molded Oxford style boot**

**Insert Modification (as needed)**
Semi-rigid or rigid functional orthosis, Additional accommodative padding as needed, Ankle-foot orthosis or other stabilization and/or immobilization brace

**Comments**
The type of shoe and orthotic must be determined based on the severity of the pathology.

**Pathology**

**Shoe Type**
Stock shoes* Oxford style boot** Depth shoe Custom molded

**Insert Modification (as needed)**
Semi-rigid or rigid functional orthosis, Additional accommodative padding as needed, Ankle-foot orthosis or other stabilization and/or immobilization brace, Heel cup

**Comments**
The type of shoe and orthotic must be determined based on the severity of the pathology.

**Pathology**
Diabetic neuropathology with no concomitant deformities

**Shoe Type**
Depth shoe

**Insert Modification (as needed)**
Over the Counter (OTC), OTC Accommodation Orthoses, Semi-rigid or rigid functional orthosis, Additional accommodative padding as needed.

**Comments**
As a preventive measure, this group of patients should be followed on a regular basis for the development of pathology to ensure quick interventions as needed.

**Pathology**
Peripheral vascular disease with non concomitant deformities (arterial or venous)

**Shoe Type**
Depth shoe

**Insert Modification (as needed)**
OTC, OTC Accommodation Orthoses, Semi-rigid or rigid functional orthosis, Additional accommodative padding as needed

**Comments**
As a preventive measure, this group of patients should be followed on a regular basis for the development of pathology.
Pathology
Digital and midtarsal amputations

Shoe Type
Depth shoe Custom molded

Insert Modification (as needed)
Semi-rigid or rigid functional orthosis, Appropriate Filler, Additional accommodative padding as needed

Comments
As a preventive measure, this group of patients should be followed on a regular basis for the development of pathology.
Adapted from VHA, 2004.
* Stock shoes include standard therapeutic Oxford dress, casual or walking shoes.
** Certain conditions and circumstances may require the use of boots that add ankle support.

Reviewed by a Board Certified Internist
Reviewed by David Evans, MD, Medical Director, Active Health Management- July 2016
Copyright 2016 ACTIVEHEALTH MANAGEMENT
No part of this document may be reproduced without permission.

Footnotes

[A] Foot orthotics have no proven value for back pain, knee pain (other than medial osteoarthritis), pes planus (flat feet), pronation, corns and calluses, hammertoes, hip osteoarthritis, and lower leg injuries. [A in Context Link 1]

[B] Note: Coverage is provided for a pair of diabetic shoes even if only 1 foot suffers from diabetic foot disease. [B in Context Link 1]

[C] This includes a shoe with or without an internally seamless toe. Depth shoes without these characteristics have no proven value for diabetes. [C in Context Link 1]

[D] This includes a shoe with or without an internally seamless toe. Custom-molded shoes without these characteristics have no proven value for diabetes. [D in Context Link 1]

[E] Deluxe features of therapeutic shoes have no proven value. A deluxe feature is defined as a feature that does not contribute to the therapeutic function of the shoe. It may include, but is not limited to style, color, or type of leather. [E in Context Link 1]

[F] Shoes that are an integral part of a prosthesis are considered medically necessary for members with a partial foot. [F in Context Link 1]
Codes