

Medical Policy:

Orthotics / Foot Effective: 02-27-07 Reviewed: 11-7-11; 4-17-12

Definitions:

Orthotic Device: A support or brace designed for the support of a weak or ineffective joint, muscle, or to improve the function of movable body parts.

Prosthetic Device: An artificial device used to replace a body part.

VCHCP excludes coverage of orthopedic shoes, foot orthotics or other supportive devices of the feet, except under the following conditions:

- 1. This exclusion does not apply to such a shoe if it is an integral part of a leg brace and its expense is included as part of the cost of the brace. See section below on therapeutic shoes as integral parts of a leg brace.
- 2. This exclusion does not apply to therapeutic shoes furnished to selected diabetic members. See section below on therapeutic shoes for diabetes for details.
- 3. This exclusion does not apply to rehabilitative foot orthotics that are prescribed as part of post-surgical or post-traumatic casting care.
- 4. This exclusion does not apply to prosthetic shoes. See section below on prosthetic shoes for details.

This policy is consistent with CMS guidelines. Please check benefit plan descriptions for details.

Therapeutic shoes as integral parts of a leg brace:

<u>Note</u>: Even under plans that exclude coverage of foot orthotics, VCHCP covers therapeutic shoes if they are an integral part of a covered leg brace and are medically necessary for the proper functioning of the brace. Oxford shoes are usually covered in these situations. Other shoes, e.g., high top, depth inlay or custom-molded for nondiabetic, etc. may also be covered if they are an integral part of a covered leg brace. Medically necessary heel replacements, sole replacements, and shoe transfers are also covered for therapeutic shoes that are an integral part of a covered leg brace. Inserts and other shoe modifications of shoes that are an integral part of a leg brace are covered if they are medically necessary for the proper functioning of the brace. Medically necessary shoe and related modifications, inserts, and heel/sole replacements, are covered when the shoe is an integral part of a leg brace. A matching shoe, which is not attached to the brace and items related to that shoe, is also covered.

Shoes that are billed separately (i.e., not as part of a brace) will not be covered even if they are later incorporated into a brace.

Therapeutic shoes for diabetes:

Note on Diabetic Shoe Benefit: Medically necessary foot orthotics may be covered for diabetic members.

VCHCP considers therapeutic shoes (depth or custom-molded) along with inserts medically necessary for members with diabetes mellitus and *any* of the following complications involving the foot:

- 1. Peripheral neuropathy with evidence of callus formation; or
- 2. History of pre-ulcerative calluses; or
- 3. History of previous ulceration; or
- 4. Foot deformity; or
- 5. Previous amputation of the foot or part of the foot; or
- 6. Poor circulation.

These criteria are consistent with CMS guidelines.

One of the following per member per calendar year is considered medically necessary:

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

The following items are considered medically necessary for persons with diabetes who meet the criteria for diabetic shoes listed above:

- 1. Depth shoes with the following characteristics are considered medically necessary when criteria are met:
 - 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; *and*
 - Are made of leather or other suitable material of equal quality; and
 - Have some sort of shoe closure; *and*
 - Are available in full and half sizes with a minimum of three 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).

This includes a shoe with or without an internally seamless toe.

2. Custom-molded shoes with the following characteristics are considered medically necessary when the member has a foot deformity that cannot be accommodated by a depth shoe:

- Constructed over a positive model of the member's foot; and
- Made from leather or other suitable material of equal quality; and
- Have removable inserts that can be altered or replaced as the member's condition warrants; *and*
- Have some sort of shoe closure.

This includes a shoe with or without an internally seamless toe.

- 3. Modifications of custom-molded and depth shoes: An individual may substitute modifications of custom-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.) 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.
 - Rigid rocker bottoms: These are exterior elevations with apex positions for 51 percent to 75 percent 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.
 - 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.
 - 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.
 - 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.
- 4. Other medically necessary modifications to diabetic shoes include, but are not limited to:
 - Flared heels;
 - Velcro closures; and
 - Inserts for missing toes.

VCHCP does *not* consider deluxe features to therapeutic shoes medically necessary. 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.

<u>Note</u>: Coverage is provided for a pair of diabetic shoes even if only one foot suffers from diabetic foot disease.

Prosthetic shoes:

A prosthetic shoe is a device used when all or a substantial portion of the front part of the foot is missing. VCHCP considers shoes that are an integral part of a prosthesis medically necessary for members with a partial foot. <u>Note</u>: VCHCP does *not* cover stock shoes that are put on over a partial foot or other lower extremity prosthesis.

<u>Note</u>: Medically necessary prosthetic shoes are covered even under VCHCP plans that exclude foot orthotics. The function of a prosthetic shoe is quite distinct from that of excluded orthopedic shoes and supportive foot devices that are used by individuals whose feet, although impaired, are essentially intact. Please check benefit plan descriptions for details.

Rehabilitative foot orthotics following surgery or trauma:

<u>Note</u>: Even under plans that exclude coverage of foot orthotics, VCHCP covers rehabilitative foot orthotics that are prescribed following foot surgery or trauma when the these rehabilitative foot orthotics are medically necessary as part of post surgical or casting care. In these instances, foot orthotics are considered an integral part of the covered surgical procedure or foot trauma repair. For example, VCHCP covers foot orthotics for infants and toddlers who have foot orthotics applied during the rehabilitative period immediately following surgery for congenital foot deformities and are receiving these foot orthotics as part of the post surgery or casting care.

Shoe modifications and replacements:

Medical necessity criteria for replacements of or modifications to existing customized shoes are 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. Replacement of orthotics is generally not necessary more often than every two years.

Other medical necessity limitations:

Orthotic devices made on the same date as an open cutting surgical procedure (e.g., bunionectomy) are not considered medically necessary.

Only one orthotic per foot is considered medically necessary.

Separate orthotics for each pair of the member's shoes are not considered medically necessary.

Background

<u>Orthotic shoes or orthopedic shoes</u>: 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: 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 Shoe:a walking aid for patients with multiple sclerosis.

Straight Last Shoe:a corrective splint for metatarsus adductus.

<u>Modifications of stock shoes</u>: 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).

<u>Internal shoe modifications</u>: 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 running 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 $\frac{3}{4}$ " wide by $\frac{2}{8}$ " - $\frac{3}{8}$ " 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.

<u>Plates</u>: 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 firth 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 custommade rigid orthotic to stabilize the foot.

<u>Foot orthoses</u>: 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 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 longlasting, 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.

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 weightbearing 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 stirrup 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.

<u>Hip-knee-ankle-foot orthoses</u>: 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.

<u>Fracture orthoses</u>: 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.

A. Attachments: None

B. **History**:

- a. Reviewer/Author: Cynthian Wilhelmy, MD Date: 01-16-07
- b. Committee Review: UM on 02-20-07 & QA on 02-27-07
- c. **Reviewed/No Changes by**: Faustine Dela Cruz, RN & Albert Reeves, MD Date: 11-7-11
- d. Committee Review: UM on 11.10.11 & QA on 11.22.11
- e. Reviewed/No Changes: Albert Reeves, MD Date: 4-17-12
- f. Committee Reviews: UM on 5-10-12 & QA on 5-22-12

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