

Diabetic Shoes and Inserts

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Introduction

Diabetic shoes, inserts, and modifications are addressed by this guideline.

Criteria

Initial Request

- Therapeutic diabetic shoes, inserts, and/or modifications are medically necessary when **all** of the following are present:
 - The individual has diabetes mellitus.
 - The certifying provider has documented in the individual's medical record (or has noted agreement with podiatry documentation) **any** of the following foot conditions:
 - Deformity of either foot (e.g., hammer toe deformity, mallet toe deformity, Charcot arthropathy).
 - History of pre-ulcerative callus(es) of either foot.
 - Peripheral neuropathy in the feet.
 - Poor circulation in either or both feet.
 - History of amputation of the foot or part of either foot.
 - History of ulceration of either foot.
 - Prevention of foot ulceration or amputation is needed.
 - There is no active, untreated plantar foot ulcer.
 - The individual has ongoing participation in a comprehensive, physician-directed diabetes management program.
 - There is documentation of examination of the individual's feet with a description of the abnormalities that will be accommodated by the shoes, inserts, and/or modifications.

Additional Information

- Custom-molded shoes (HCPCS A5501) may be medically necessary when the individual has a foot deformity that cannot be accommodated by depth shoes (HCPCS A5500).

- A modification of a custom molded or depth shoe may be medically necessary as a substitute for an insert.

Quantity Limits and Coding Considerations

- For individuals meeting the coverage criteria, coverage is limited to **one** of the following within one calendar year (January – December):
 - One pair of depth shoes (HCPCS A5500) and three pairs of inserts (HCPCS A5512, A5513, or A5514).
 - One pair of custom molded shoes (HCPCS A5501) (which includes inserts) and two additional pairs of inserts (HCPCS A5512, A5513, or A5514).
- Codes for inserts or modifications (HCPCS codes A5503, A5504, A5505, A5506, A5507, A5508, A5510, A5512, A5513, A5514) may only be used for items related to diabetic shoes (HCPCS codes A5500, A5501).

Not Covered

- A deluxe feature of a diabetic shoe (HCPCS A5508) is considered not medically necessary as it does not contribute to the therapeutic function of the shoe. It may include, but is not limited to: style, color, or type of leather.

Definitions

Diabetes Mellitus (DM) describes diseases of abnormal carbohydrate metabolism that are characterized by hyperglycemia. DM is associated with a relative or absolute impairment in insulin secretion, along with varying degrees of peripheral resistance to the action of insulin.

Diabetic peripheral neuropathy is nerve damage from diabetes that can cause tingling, pain, numbness, and/or weakness in feet and hands.

Peripheral vascular disease (PVD) describes problems with blocked blood vessels disrupting the flow of blood. Peripheral artery disease (PAD) is a type of PVD.

Peripheral artery disease (PAD) is a disease of the large blood vessels of the arms or legs. Peripheral artery disease may occur when major blood vessels are blocked and do not receive enough blood. The signs of peripheral artery disease are aching pains and slow-healing foot sores.

Charcot neuro-arthropathy of the foot is a condition in which the joints and soft tissue in the foot are destroyed.

Gangrene is the death of body tissue, most often caused by a lack of blood flow and infection, which may lead to amputation.

Osteomyelitis is an infection in a bone.

Diabetic foot ulcer (DFU) is a debilitating and severe manifestation of uncontrolled and prolonged diabetes that presents as ulceration, usually located on the plantar aspect of the foot.

A **certifying provider** is a doctor (MD/DO), nurse practitioner (NP), or physician's assistant (PA) who manages systemic conditions such as diabetes. The certifying provider develops a comprehensive plan and follows an individual through the continuum of care.

A **Podiatrist** is a doctor who treats people who have foot problems. Podiatrists also help people keep their feet healthy by providing regular foot examinations and treatment.

Diabetic shoes are made from leather or other suitable material of equal quality, and have some form of shoe closures.

- A **depth shoe** (HCPCS code A5500) has a full length heel-to-toe filler that, when removed, provides a minimum of 3/16-inch of additional depth used to accommodate custom-molded or customized inserts.
- A **custom-molded shoe** (HCPCS code A5501) is constructed over a positive model of the individual's foot. The custom-molded shoe has removable inserts that can be altered or replaced.

HCPCS code A5512 describes a total contact, multiple density, prefabricated removable inlay that is directly molded to the individual's foot.

HCPCS code A5513 describes a total contact, custom-fabricated, multiple density, removable inlay that is molded to a model of the individual's foot so that it conforms to the plantar surface and makes total contact with the foot, including the arch. A custom-fabricated device is made from materials that do not have predefined trim lines for heel cup height, arch height and length, or toe shape.

HCPCS code A5514 describes a total contact, custom-fabricated, multiple density, removable inlay that is directly milled from a rectified virtual model of the individual's foot so that it conforms to the plantar surface and makes total contact with the foot, including the arch. A custom-fabricated device is made from materials that do not have predefined trim line for heel cup height, arch height and length, or toe shape.

Modifications of depth and custom-molded shoes further adapt the footwear and insole for more effective targeted pressure relief, which may include, but are not limited to:

- **Rigid rocker bottoms (HCPCS code A5503)** are exterior elevations with apex position for 51% to 75% distance measured from the back end of the heel to eliminate pressure at the metatarsal heads. Rigidity is ensured by the steel in the shoe.
- **Wedges (posting) (HCPCS code A5504)** are either of hind foot, forefoot, or both and may be in the middle or laterally. The function is to transfer weight bearing upon standing or during ambulation to the opposite side for stabilization and balance.

- **Metatarsal bars (HCPCS code A5505)** are exterior bars that function to remove pressure from the metatarsal heads. The bars are of various shapes, heights, and construction depending on the exact purpose.
- **Offset heels (HCPCS code A5506)** are flanged at the base either in the middle, to the side, or a combination, which is then extended upward to the shoe in order to stabilize extreme positions of the hind foot.

Evidence Discussion

Purpose of technology/description of device

Therapeutic diabetic shoes aim to reduce the risk of foot ulceration or amputation in high-risk diabetic individuals. These custom-made shoes are designed to protect the foot, relieve areas of excess pressure, reduce shock and shear, accommodate deformities, and allow for the use of customized inserts.

Previous diabetic foot ulcers are associated with a higher risk of recurrent foot ulcer, while a previous foot amputation is associated with a higher risk of both diabetic foot ulcer and reamputation. Diabetic foot ulcers result in amputation in 10% to 20% of cases; 60% of individuals with a prior diabetic foot ulcer will have a recurrence of ulceration if using self-selected shoes.

Medical background

The United States Food and Drug Administration (FDA) considers diabetic shoes and inserts to be Class I devices. As such, they are considered to be of low to moderate risk, and they are subject to the least regulatory control. Manufacturers of diabetic shoes and inserts available in the United States include Apex®, Cadense®, Dr. Comfort®, Kizik®, and Orthofeet®.

Literature review

- van Netten et al. (2020) performed a systematic review of the literature to investigate the effectiveness of therapeutic footwear interventions to prevent first-ever or recurrent diabetic foot ulcers. The authors examined multiple interventions including therapeutic footwear (e.g., shoes, insoles, and orthoses) and walking aids (e.g., crutches). The review included seven randomized controlled trials, three cohort studies, and nine noncontrolled studies. The authors reported a low level of evidence that therapeutic footwear may reduce the risk of first-ever ulcer in diabetic individuals. Moreover, the authors reported a moderate level of evidence of the benefit of therapeutic footwear for the prevention of recurrent diabetic plantar foot ulcers. Thus, the authors concluded that custom-made therapeutic footwear may be beneficial for improving modifiable risk factors for foot ulceration.

- Yalla et al. (2020) reviewed the current literature on offloading of the diabetic foot. The article summarized The International Working Group on the Diabetic Foot (IWGDF) evidence-based guidelines regarding the use of offloading footwear for prevention and treatment of diabetic foot ulcers. The authors noted that footwear should be evaluated by trained professionals because individuals with diabetic peripheral neuropathy-induced loss of protective sensation cannot adequately assess fit. Moreover, therapeutic footwear with a plantar pressure-relieving effect should be prescribed for individuals at high or moderate risk for diabetic foot ulcer. Individuals at high risk are those with either loss of protective sensation or peripheral arterial disease, and a history of prior foot ulceration, lower extremity amputation, and/or end-stage renal disease. Those at moderate risk have at least two of the known risk factors, including loss of protective sensation, peripheral arterial disease, and foot deformity. In summary, the authors noted that custom-made accommodative orthoses and therapeutic footwear are effective at preventing ulcer recurrence in diabetic individuals when used consistently.
- In 2022, Waibel and Böni performed a literature review of the non-operative treatment strategies for Charcot neuro-osteoarthropathy (CN). The authors noted that when CN has resolved, fitting of orthopedic depth insoles, orthopedic shoes, or ankle-foot orthosis should follow immediately after offloading has ended to prevent CN reactivation or ulcer development. Patients may be fitted with depth-inlay shoes combined with either off-the-shelf or custom-made foot orthoses and a stiff walking sole including a rocker bottom. The authors cited a study by Zwaferink and colleagues (2020) that investigated the efficacy of custom-made footwear in the prevention of diabetic foot ulceration. In this study, 24 neuropathic diabetic patients were measured for in-shoe plantar pressures during walking in four custom-made footwear conditions. The authors found that all footwear conditions significantly reduced metatarsal head peak pressure compared with the non-therapeutic shoe, thus demonstrating the offloading efficacy of custom-made footwear for plantar foot ulcer prevention.
- Elraiayah et al. (2016) conducted a systematic review to evaluate the methods of off-loading in the prevention of diabetic ulcers. The review included 13 randomized controlled trials, including data from 1605 patients with diabetic foot ulcers using an off-loading method. Primary outcomes of interest included complete wound healing, time to complete wound healing, amputation, infection, and relapse rates. Meta-analysis of four studies showed that therapeutic shoes and insoles significantly reduced ulcer relapse rate compared with regular footwear. Thus, the authors reported a low level of evidence that therapeutic shoes and insoles provided a benefit in reducing ulcer relapse rate.

Professional organizations/societies

- A 2020 professional society consensus guideline (Bus et al.) developed a pressure relief algorithm for custom-made footwear for moderate- to high-risk patients

with diabetes and peripheral neuropathy. Fourteen domains of foot pathology in combination with loss of protective sensation were specified for the footwear design algorithm. For each domain, shoe-specific and insole-specific features were defined. Most insole-related features and some shoe-related features were evidence-based, whereas most shoe-related features were consensus based. The pressure relief algorithm was evidence-based using recent footwear trial data, and specifically targeted patients with a healed plantar foot ulcer.

- A 2018 update to the Australian footwear guideline (van Netten et al.) formulated 10 recommendations for health professionals in the management and selection of footwear for patients with diabetes, including: "(1) Advise people with diabetes to wear footwear that fits, protects and accommodates the shape of their feet. (2) Advise people with diabetes to always wear socks within their footwear, in order to reduce shear and friction. (3) Educate people with diabetes, their relatives and caregivers on the importance of wearing appropriate footwear to prevent foot ulceration. (4) Instruct people with diabetes at intermediate- or high-risk of foot ulceration to obtain footwear from an appropriately trained professional to ensure it fits, protects and accommodates the shape of their feet. (5) Motivate people with diabetes at intermediate- or high-risk of foot ulceration to wear their footwear at all times, both indoors and outdoors. (6) Motivate people with diabetes at intermediate- or high-risk of foot ulceration (or their relatives and caregivers) to check their footwear, each time before wearing, to ensure that there are no foreign objects in, or penetrating, the footwear; and check their feet, each time their footwear is removed, to ensure there are no signs of abnormal pressure, trauma or ulceration. (7) For people with a foot deformity or pre-ulcerative lesion, consider prescribing medical grade footwear, which may include custom-made in-shoe orthoses or insoles. (8) For people with a healed plantar foot ulcer, prescribe medical grade footwear with custom-made in-shoe orthoses or insoles with a demonstrated plantar pressure relieving effect at high-risk areas. (9) Review prescribed footwear every three months to ensure it still fits adequately, protects, and supports the foot. (10) For people with a plantar diabetic foot ulcer, footwear is not specifically recommended for treatment; prescribe appropriate offloading devices to heal these ulcers."
- The 2022 American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan (Blonde et al.) reported that most foot ulcerations had a neuropathic component and are preventable by foot care that includes daily inspection, nail and skin care, correction of foot deformities, and/or provision of appropriate footwear to accommodate structural changes.
- An 2016 update to the guidelines for the treatment of diabetic foot ulcers by the Wound Healing Society (WHS) (Lavery et al.) recommended that protective footwear should be prescribed in any patient at risk for amputation (e.g., significant arterial insufficiency, significant neuropathy, previous amputation, previous ulcer formation, pre-ulcerative callus, foot deformity, evidence of callus formation). Moreover, the authors noted that long-term offloading was necessary to decrease the pressure on

the foot. Thus, the authors reported Level 1 evidence that protective footwear resulted in the reduction of recurrent ulcerations in high-risk patients with a previous foot ulcer or amputation.

- A multidisciplinary clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine (Hingorani et al., 2016) provided specific practice recommendations based on five systematic reviews of the literature. Specific areas of focus included (1) prevention of diabetic foot ulceration, (2) off-loading, (3) diagnosis of osteomyelitis, (4) wound care, and (5) peripheral arterial disease. The authors recommended using custom therapeutic footwear in high-risk diabetic patients, including those with significant neuropathy, foot deformities, or previous amputation.

Codes addressed in this guideline

The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

HCPCS code	Description
A5500	For diabetics only, fitting (including follow-up), custom preparation and supply of off-the-shelf depth-inlay shoe manufactured to accommodate multi-density insert(s), per shoe
A5501	For diabetics only, fitting (including follow-up), custom preparation and supply of shoe molded from cast(s) of patient's foot (custom molded shoe), per shoe
A5503	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with roller or rigid rocker bottom, per shoe
A5504	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with wedge(s), per shoe
A5505	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with metatarsal bar, per shoe
A5506	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with off-set heel(s), per shoe

HCPSC code	Description
A5507	For diabetics only, not otherwise specified modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe, per shoe
A5508	For diabetics only, deluxe feature of off-the-shelf depth-inlay shoe or custom-molded shoe, per shoe
A5510	For diabetics only, direct formed, compression molded to patient's foot without external heat source, multiple-density insert(s) prefabricated, per shoe
A5512	For diabetics only, multiple density insert, direct formed, molded to foot after external heat source of 230 degrees fahrenheit or higher, total contact with patient's foot, including arch, base layer minimum of 1/4 inch material of shore a 35 durometer or 3/16 inch material of shore a 40 durometer (or higher), prefabricated, each
A5513	For diabetics only, multiple density insert, custom molded from model of patient's foot, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer (or higher), includes arch filler and other shaping material, custom fabricated, each
A5514	For diabetics only, multiple density insert, made by direct carving with cam technology from a rectified cad model created from a digitized scan of the patient, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer (or higher), includes arch filler and other shaping material, custom fabricated, each

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