

Diabetic Shoes and Inserts

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Introduction

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

Criteria

- Therapeutic diabetic shoes, inserts, and/or modifications are considered 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 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) are considered 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 is considered medically necessary as a substitute for an insert.

Quality 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.

Health Equity Considerations

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

Diabetes is a chronic metabolic disease characterized by an impaired ability of the body to produce or respond to insulin and maintain proper levels of glucose in the bloodstream. According to the Centers for Disease Control and Prevention (CDC), 1.2 million Americans are diagnosed with diabetes annually, and 12% of those are non-Hispanic Blacks (CDC, 2024). There are multiple complications associated with diabetes, including macrovascular complications, nephropathy, neuropathy, retinopathy and foot ulceration (Acute and Chronic Complications | American Diabetes Association, n.d.). In McDermott et al. (2022) the authors state "the lifetime risk of foot ulcer is 19% to 34%, and this number is rising with increased longevity and medical complexity of people with diabetes. Morbidity following incident ulceration is high, with recurrence rates of 65% at 3–5 years, lifetime lower-extremity amputation incidence of 20%, and 5-year mortality of 50–70 %." (McDermott et al., 2022) Risk factors for foot ulcerations include a loss of protective sensation, peripheral artery disease and foot deformity (Bus et. al, 2023). Examples of various interventions available for the prevention of foot ulcers are inspecting the feet regularly, education and the routine use of foot care, including

correct footwear and orthoses. Options for diabetic footwear include custom-made insoles, medical grade footwear, in-shoe (semi)-rigid orthosis, and prefabricated insoles and footwear (Bus et. al, 2023, Clayton et. al, 2023). According to the America Diabetes Association, diabetic footwear is constructed with materials that stretch without causing pressure or irritation, has increased stability and support for walking, and is lightweight to improve circulation and movement. In addition, the extra-depth feature provides room for orthotics and custom insoles (Diabetes.org, 2022).

Appropriate diabetic footwear can reduce ulcer risk by 37% with adherence (Bus et. al, 2023). Individuals in the lowest income brackets may struggle with obtaining the diabetic footwear needed to prevent and manage their diabetic foot ulcers including therapeutic shoes and insoles. Barriers to accessing appropriate medical equipment include lack of insurance, out of pocket expenses, significant lead time to completion and travel distance to obtain the devices (Tan et. al, 2022). Racial and ethnic disparities need to be addressed to deliver appropriate care among minority groups to avoid life altering foot ulcer complications.

Evidence Discussion

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 non-controlled 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. Individuals 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 individuals 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

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 individuals 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 individuals 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 individuals, including those with significant neuropathy, foot deformities, or previous amputation.

Codes addressed in this guideline

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

HCP code	Description
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
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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