Clinical Practice Guideline: **Diabetic Shoes/Inserts**

Date of Implementation: **December 18, 2015**

Product: **Specialty**

GUIDELINES

A. American Specialty Health – Specialty (ASH) considers therapeutic shoes and inserts described by HCPCS Codes A5500, A5501, A5512, and A5513 to be medically necessary when **ALL of the following** criteria are met:

1. The patient has a diagnosis of diabetes mellitus as indicated by the diagnosis codes listed below:

Diagnosis Code	Diagnosis Code Description
E08.00, E08.10 – E08.29, E08.311 – E08.3599, E08.36 – E08.59, E08.610 – E08.628, E08.649, E08.65 – E08.69, E08.8 – E08.9	Diabetes mellitus due to underlying condition
E09.00, E09.10, E09.21 – E09.29, E09.311 – E09.3599, E09.36 – E09.59, E09.610 – E09.628, E09.649, E09.65 – E09.69, E09.8 – E09.9	Drug or chemical induced diabetes mellitus
E10.10, E10.21 – E10.29, E10.311 – E10.3599, E10.36 – E10.59, E10.610 – E10.628, E10.649, E10.65 – E10.69, E10.8 – E10.9	Type 1 diabetes mellitus

Diagnosis Code	Diagnosis Code Description
E11.00, E11.21 – E11.29, E11.311 – E11.3599, E11.36 – E11.59, E11.610 – E11.628, E11.649, E11.65 –E11.69, E11.8 – E11.9	Type 2 diabetes mellitus
E13.00, E13.10, E13.21 – E13.29, E13.311 – E13.3599, E13.36 – E13.59, E13.610 – E13.628, E13.649, E13.65 – E13.69, E13.8 – E13.9	Other specified diabetes mellitus

2. The certifying physician has documented in the patient's record* a foot condition, as indicated by **1 or more of the following**:
    a. Previous amputation of the other foot, or part of either
    b. History of previous foot ulceration of either foot
    c. History of pre-ulcerative calluses of either foot
    d. Peripheral neuropathy with evidence of callus formation of either foot
    e. Foot deformity of either foot
    f. Poor circulation in either foot

3. The certifying physician has certified that indications (1) and (2) above are met and that he/she is treating the patient under a comprehensive plan of care for his/her diabetes and that the patient needs diabetic shoe(s). The certifying physician must:
    - Have an in-person visit with the patient during which diabetes management is addressed within 6 months prior to delivery of the shoes/inserts; and
    - Sign the certification statement on or after the date of the in-person visit and within 3 months prior to delivery of the shoes/inserts.

4. Prior to selecting the specific items that will be provided; the supplier must conduct and document an in-person evaluation of the patient.
    - The in-person evaluation of the patient by the supplier at the time of selecting the items that will be provided must include at least the following:
        a) An examination of the beneficiary's feet with a description of the abnormalities that will need to be accommodated by the shoes/inserts/modifications.
        b) For all shoes, taking measurements of the patient's feet.
        c) For custom molded shoes (A5501) and inserts (A5513), taking impressions, making casts, or obtaining CAD-CAM images of the patient's feet that will be used in creating positive models of the feet.

5. At the time of in-person delivery to the patient of the items selected, the supplier must conduct an objective assessment of the fit of the shoe and inserts and document the results. A patient's subjective statements regarding fit as the sole documentation of the in-person delivery does not meet this criterion.

*In order to meet criterion 2, the certifying physician must either:

- Personally document one or more of criteria a – f in the medical record of an in-person visit within 6 months prior to delivery of the shoes/inserts and prior to or on the same day as signing the certification statement; or
- Obtain, initial, date (prior to signing the certification statement), and indicate agreement with information from the medical records of an in-person visit with a podiatrist, medical or osteopathic physician, physician assistant, nurse practitioner, or clinical nurse specialist that is within 6 months prior to delivery of the shoes/inserts, and that documents one of more of criteria a – f.

For patients meeting the above criteria, coverage is limited to one of the following per calendar year:

- One pair of depth shoe(s) (A5500) and 3 pairs of inserts (A5512 or A5513) (not including the non-customized removable inserts provided with such shoes; or
- One pair of custom molded shoes (A5501) (which includes inserts provided with these shoes) and 2 additional pairs of inserts (A5512 or A5513).

The certifying physician evaluation and management (HCPCS codes G0245 or G0246) of diabetic patients with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS), in accordance with the criteria listed above, must include: (1) the diagnosis of LOPS, (2) a patient history, (3) a physical examination that consists of at least the following elements: (a) visual inspection of the forefoot, hindfoot, and toe web spaces, (b) evaluation of a protective sensation, (c) evaluation of foot structure and biomechanics, (d) evaluation of vascular status and skin integrity, and (e) evaluation and recommendation of footwear, and (4) patient education.

The Certifying Physician is defined as a Doctor of Medicine (M.D.) or a doctor of osteopathy (D.O.) who is responsible for diagnosing and treating the beneficiary's diabetic systemic condition through a comprehensive plan of care. The certifying physician may not be a podiatrist, physician assistant, nurse practitioner, or clinical nurse specialist.

The Prescribing Physician is the person who actually writes the order for the therapeutic shoe, modifications and inserts. This physician must be knowledgeable in the fitting of diabetic shoes and inserts. The prescribing physician may be a podiatrist, M.D., D.O., physician assistant, nurse practitioner, or clinical nurse specialist. The prescribing physician may be the supplier (i.e., the one who furnishes the footwear).

The Supplier is the person or entity that actually furnishes the shoe, modification, and/or insert to the beneficiary and that bills Medicare. The supplier may be a podiatrist, pedorthist, orthotist, prosthetist or other qualified individual. The Prescribing Physician may be the supplier. The Certifying Physician may only be the supplier if the certifying physician is practicing in a defined rural area or a defined health professional shortage area.

A deluxe feature (A5508) does not contribute to the therapeutic function of the shoe. Deluxe features of diabetic shoes (A5508) will be denied as noncovered.

These criteria are consistent with the Centers for Medicare & Medicaid Services (CMS) guidelines.

HCPCS CODES AND DESCRIPTIONS

HCPCS Code	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 multidensity 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
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

HCPCS Code	HCPCS Code Description
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
G0245	Initial physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include: (1) the diagnosis of LOPS, (2) a patient history, (3) a physical examination that consists of at least the following elements: (a) visual inspection of the forefoot, hindfoot, and toe web spaces, (b) evaluation of a protective sensation, (c) evaluation of foot structure and biomechanics, (d) evaluation of vascular status and skin integrity, and (e) evaluation and recommendation of footwear, and (4) patient education
G0246	Follow-up physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include at least the following: (1) a patient history, (2) a physical examination that includes: (a) visual inspection of the forefoot, hindfoot, and toe web spaces, (b) evaluation of protective sensation, (c) evaluation of foot structure and biomechanics, (d) evaluation of vascular status and skin integrity, and (e) evaluation and recommendation of footwear, and (3) patient education

BACKGROUND

Diabetic foot disease results in significant morbidity, mortality, and health care cost. Foot ulcerations, infections, peripheral neuropathy, and lower extremity amputations are some of the common consequences of diabetes. Regular nail care, callus removal, and education can prevent plantar ulceration. Additionally, protective footwear and custom orthotics improve function by reducing force and shear impact on the fragile foot and accommodate the patient's deformities.

Therapeutic Shoes/Inserts for Diabetics

A depth shoe (A5500) is one that has a full length, heel-to-toe filler that when removed provides a minimum of 3/16" of additional depth used to accommodate custom-molded or customized inserts. It is made from leather or other suitable material of equal quality; and has some form of shoe closure. It is 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 shoe according to the American standard last sizing schedule or its equivalent (The American

last sizing schedule is the numerical shoe sizing system used for shoes in the United States). The depth shoe may or may not have an internally seamless toe.

A custom-molded shoe (A5501) is constructed over a positive model of the patient's foot. It is made from leather or other suitable material of equal quality and has removable inserts that can be altered or replaced as the patient's condition warrants. This shoe has some form of shoe closure and may or may not have an internally seamless toe.

Code A5512 describes a total contact, multiple density, prefabricated removable inlay that is directly molded to the beneficiary's foot. Direct molded means it has been conformed by molding directly to match the plantar surface of the individual beneficiary's foot. Total contact means it makes and retains actual and continuous physical contact with the weight-bearing portions of the foot, including the arch throughout the standing and walking phases of gait.

The insert must retain its shape during use for the life of the insert. The layer responsible for shape retention is called the "base layer" in the code descriptor. This material usually constitutes the bottom layer of the device and must be of a sufficient thickness and durometer to maintain its shape during use (i.e., at least ¼ inch of 35 Shore A or higher or at least 3/16 inch of 40 Shore A or higher). The material responsible for maintaining the shape of the device must be heat moldable. The specified thickness of the base layer must extend from the heel through the distal metatarsals and may be absent at the toes.

Code A5513 describes a total contact, custom fabricated, multiple density, and removable inlay that is molded to a model of the beneficiary'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.

The insert must retain its shape during use for the life of the insert. The base layer of the device must be at least 3/16 inch of 35 Shore A or higher material. The base layer is allowed to be thinner in the custom fabricated device because appropriate arch fill or other additional material will be layered up individually to maintain shape and achieve total contact and accommodate each beneficiary's specific needs. The central portion of the base layer of the heel may be thinner (but at least 1/16 inch) to allow for greater pressure reduction. The specified thickness of the lateral portions of the base layer must extend from the heel through the distal metatarsals and may be absent at the toes. The top layer of the device may be of a lower durometer and must also be heat moldable. The materials used should be suitable with regards to the beneficiary's condition.

Codes for inserts or modifications (A5512 and A5513) may only be used for items related to diabetic shoes (A5500 or A5501).

EVIDENCE REVIEW

Diabetic Foot Ulcers and Orthotics

Diabetic foot ulcers are a serious issue and have many functional implications. Spencer (2000) completed a Cochrane Systematic Review on the pressure-relieving interventions used for preventing or treating these foot ulcers. Five (5) total RCTs met the inclusion criteria: 4 for prevention and 1 for treatment. The studies for prevention of foot ulcers suggested that in-shoe orthotics are beneficial as a sole intervention when comparing different types of orthotics, and as compared to removal of the callus. They could not conclude whether it was the cushioning or the pressure re-distribution that provided the positive outcomes, as the data indicated equality of the two. Many other pressure-relieving methods (e.g., removable casts or foam inlays) have not been investigated adequately. For the one study on treatment of ulcers, contact casting indicated positive results, but evidence was limited. More research is needed to effectively demonstrate appropriate treatment interventions for the diabetic foot ulcer. Chevalier and Chockalingam (2012) examined the role of the practitioner in foot orthoses effectiveness. They emphasize that while foot orthoses have been shown to have positive effects in the literature for various lower extremity issues, the literature is of variable quality and outcomes. The exact mechanisms of orthotic use are not fully understood but seem to relate to reducing plantar pressure and changing biomechanics of the foot and knee. Added into this is practitioner variability in the assessment of orthoses performance. Eleven practitioners participated in this study. Each completed a clinical assessment of one subject and then created custom orthotics based on that assessment and casting in a neutral non-weight bearing position. Each subject completed ten trials (i.e., ten walks over force plates wearing each of the custom orthotics made by each of the eleven practitioners). Kinetic and kinematic data were recorded for each trial. Results demonstrated that systematic kinematic effects could be observed for the kinematic data in the sagittal plane for forefoot to hindfoot and hindfoot to tibia peak angles. This confirmed for the authors that inter-practitioner variability is a major factor in orthotic intervention for patients with various conditions. They suggest that caution be taken when considering the literature where customized orthotics are used as an intervention based on the practitioner variability noted in this study, where clinical assessments vastly differ for the same patient. Evidence in the published scientific literature does not demonstrate a clear advantage of one treatment over another. Experts generally recommend that conservative therapy should be tried first, and over-the-counter arch supports, and heel pads should be tried for most patients prior to the use of custom-fabricated devices.

Bus et al. (2015) systematically reviewed footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in patients with diabetes. Authors reviewed both controlled and non-controlled studies. They included two systematic reviews and meta-analyses, 32 randomized controlled trials, 15 other controlled studies, and another 127 non-controlled studies. Sufficient evidence of good quality supports the use of non-removable offloading to heal plantar neuropathic forefoot ulcers and therapeutic footwear

with demonstrated pressure relief that is worn by the patient to prevent plantar foot ulcer recurrence. The evidence base to support the use of other offloading interventions is still limited and of variable quality. The evidence for the use of interventions to prevent a first foot ulcer or heal ischemic, infected, non-plantar, or proximal foot ulcers is basically non-existent. High-quality controlled studies are needed in these areas.

Ahmed et al. (2020) aimed to summarize and evaluate the evidence for footwear and insole features that reduce pathological plantar pressures and the occurrence of diabetic neuropathy ulceration at the plantar forefoot in people with diabetic neuropathy.Twenty-five studies were reviewed. This involved a total of 2063 participants. Eleven studies investigated footwear, and 14 studies investigated insoles as an intervention. Six studies investigated ulcer recurrence; no study investigated the first occurrence of ulceration. The most commonly examined outcome measures were peak plantar pressure, pressure-time integral and total contact area. Methodological quality varied. Strong evidence existed for rocker soles to reduce peak plantar pressure. Moderate evidence existed for custom insoles to offload forefoot plantar pressure. There was weak evidence that insole contact area influenced plantar pressure. Authors concluded that rocker soles, custom-made insoles with metatarsal additions and a high degree of contact between the insole and foot reduce plantar pressures in a manner that may reduce ulcer occurrence. Most studies rely on reduction in plantar pressure measures as an outcome, rather than the occurrence of ulceration. There is limited evidence to inform footwear and insole interventions and prescription in this population. Further high-quality studies in this field are required.

Kaminski et al. (2022) aimed to systematically identify and adapt suitable international guidelines to the Australian context to create new Australian evidence-based guidelines on prevention of first-ever and/or recurrent diabetes-related foot ulceration (DFU). Relative to these guidelines, Recommendation 8 was adopted and states: Consider prescribing orthotic interventions, such as toe silicone or (semi-)rigid orthotic devices, to help reduce abundant callus in a person with diabetes who is at risk for foot ulceration. Moon et al. (2023) concluded that, based on the literature, to prevent diabetic foot ulcers, practitioners should regularly screen patients for the presence of neuropathy as well as neuroarthropathies and prescribe the appropriate shoes and orthotics based on the best available clinical evidence. Although not widely available, there is potential for data-driven customization of orthotics and shoe wear based on plantar pressure data to prevent the development of diabetic foot ulcers more effectively, and ultimately prevent lower limb amputations.

PRACTITIONER SCOPE AND TRAINING

Practitioners should practice only in the areas in which they are competent based on their education, training and experience. Levels of education, experience, and proficiency may vary among individual practitioners. It is ethically and legally incumbent on a practitioner

to determine where they have the knowledge and skills necessary to perform such services and whether the services are within their scope of practice.

It is best practice for the practitioner to appropriately render services to a member only if they are trained, equally skilled, and adequately competent to deliver a service compared to others trained to perform the same procedure. If the service would be most competently delivered by another health care practitioner who has more skill and training, it would be best practice to refer the member to the more expert practitioner.

Best practice can be defined as a clinical, scientific, or professional technique, method, or process that is typically evidence-based and consensus driven and is recognized by a majority of professionals in a particular field as more effective at delivering a particular outcome than any other practice (Joint Commission International Accreditation Standards for Hospitals, 2020).

Depending on the practitioner's scope of practice, training, and experience, a member's condition and/or symptoms during examination or the course of treatment may indicate the need for referral to another practitioner or even emergency care. In such cases it is prudent for the practitioner to refer the member for appropriate co-management (e.g., to their primary care physician) or if immediate emergency care is warranted, to contact 911 as appropriate. See the *Managing Medical Emergencies (CPG 159 – S)* clinical practice guideline for information.

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