Therapeutic Shoes for Diabetics Are Proven to Be Helpful: So Why Aren't They Prescribed More?

Here's how to tackle the barriers to patient usage.

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Overview of Medicare's Therapeutic Shoe Program for People with Diabetes

The Therapeutic Shoe Program for Persons with Diabetes was introduced in 1993 and represented one of Medicare's first initiatives to provide coverage as a preventative approach to care. Its origin was based on the high cost of treating diabetic foot wounds, the increasing prevalence of diabetes, and recognition of the importance of a team approach to care. The Program provides coverage for people with diabetes and at least one other risk factor for foot ulceration, for shoes and inserts on an annual basis. Medicare determined that paying for shoes and inserts did not lead to an increase in the cost of care. Recent studies support the original premise of the evidence-based effectiveness of footwear in ulcer prevention for people with diabetes and provides strong evidence on the importance wearing therapeutic footwear.[1-4]

According to the CDC, over 40% of the U.S. population is obese. These people either have diabetes or are pre-diabetic, and as such are at increased risk of foot ulceration. The lifetime risk of a person with diabetes developing a foot ulcer is between 19% and 34%.[5] As reported by David Armstrong, in 2017, the direct costs of diabetes in the U.S. were $237 billion, a 26% increase from 2012. Approximately one-third of these costs were attributable to care for diabetic foot disease.[5-7]

Following its introduction, the Medicare diabetic shoe program grew quickly in popularity and presented podiatrists the opportunity, without violating any rules prohibiting self-referral, to work in the capacity of both a physician who prescribes shoes and inserts as well as a fitter who bills Medicare as a DMEPOS supplier. While the number of people 65 and over has gone up steadily, diabetes has become far more common, and the amount Medicare pays for shoes and inserts has increased every single year. The Medicare program has never provided coverage for shoes to more than 10% of the eligible population. In fact, while the number of people 65 and over grows every year, the number of shoes paid for by Medicare has been decreasing since 2010.

The aim of this article is to illustrate reasons for this disconnect and how podiatrists can ensure that people at risk for foot ulceration are availed care that can help them to live better, live longer, and cost insurers less.

Mechanism of Ulceration

Diabetic foot ulcers are typically caused by the repetitive stresses of ground reactive forces and friction that combine to form shear. The chance of injury is increased when there is decreased feeling in the feet and when circulation is impaired.[1]

Bony plantar prominences concentrate the pressure per unit area, and thus increase the probability of skin breakdown. Increased plantar pressure can also result from a loss of joint flexibility, abnormal foot biomechanics, and excess weight. Walking barefoot or with inappropriate footwear increases plantar pressure and the likelihood of developing ulceration. The probability of ulceration is significantly higher when there is a history of healed, prior ulceration. In one study, following healing of a previous ulcer, 40% of patients developed a wound within one year, almost 60% within three years, and 65% within five years.[5] Over half of DFUs will develop an infection. Of these, 17% will require an amputation.[5,8] The average cost of treatment per ulceration is approximately $13,000.[5]

The Role of Diabetic Footwear in Wound Prevention

To prevent ulceration, it's important that feet are protected from repetitive stresses whenever they are subject to weightbearing.[3] In one study, patients

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with diabetes and previous ulceration who wore specially designed shoes for one year had significantly fewer foot ulcer relapses (27.7 vs. 58.3%).[9]

Footwear has been described as a "visible representation of the disease". Podiatrists are often confronted with the challenge that people with diabetes at risk for foot ulceration may choose sub-optimal shoes to align with functional requirements and style preferences.[10] The protective benefits of shoes are highly dependent on balancing a number of competing considerations. Footwear can cause as well as prevent ulcerations.

Shoe Shape: The shape of the shoe should match the shape of the foot. Shoe shape is created during manufacturing by a plastic form called the shoe last. To be protective, the shape of the shoe must balance what is roomy enough to avoid excessive pressure around the foot with what is adequately aesthetically pleasing. The shoe shape must also offer enough room to fit appropriately padded socks and incorporate sufficient depth to fit an accommodative foot orthotic.

Shoe Fit: A shoe that is the "perfect" shape (if such a thing could exist), can still cause ulceration if it is not expertly fit. It's particularly important that shoe fitting be performed by a trained expert when there is decreased protective threshold or impaired circulation. Proper shoe fit means that there should be approximately 1/2" space between the end of the longest toe and the end of the shoe; the width of the shoe insole should be as wide as the foot. Too short and the tips of the toes may be subject to excessive pressure; too long or too roomy and the shoe might slip around the heel.

Wear Shoes with Accommodative inserts: Properly sized shoes offer adequate depth to accommodate the thickness of prefabricated or custom molded inserts. Pre-fabricated devices offer better cushioning, support, and shear reduction than the insoles that come standard with most shoes. If heat molded, they offer improved plantar accommodation. Custom molded inserts provide superior plantar accommodation and are especially indicated when there is a history of ulceration or when there are significant plantar prominences. When there has been partial foot amputation, a prosthesis can be incorporated with the insole to improve shoe fit.

Replace Worn Shoes/Inserts: Even perfectly-fitting, appropriately-styled shoes can fail to provide adequate protection if they are worn out. It's best to rotate wearing several pairs of shoes, alternating days, as every pair fits slightly differently and will exert different pressure on the feet. Excessive shear is usually demonstrated by redness of the skin. When detected, the cause should be determined as it may indicate that adequate accommodation is no longer being provided.

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Shoe Style: The functional requirements of shoes vary depending on the activity. People with diabetes need shoe styles for all their different activities, including shoes to be worn indoors. Sedentary people typically take more steps indoors than out and so need to have house shoes that are easy to put on and take off while still offering sufficient protection to the feet. Shoes are often seen as a visible reminder to patients that they have a condition requiring constant attention. Without adequate appreciation of their risk for foot ulceration, patients are often reluctant to make the appropriate commitment to wearing appropriate shoes, all the time. Like wearing seatbelts and bicycle helmets, taking appropriate precautions needs to become an acquired habit to ensure long-term effectiveness of reducing the chance of ulceration.

Upper Material: Rigid deformities like hammertoes and bunions may be best accommodated by a shoe shape that approximates the general foot shape yet puts undo pressure on a rigid prominence. "Bony bumps" can often be effectively accommodated if the upper material is soft and stretchy. This way, pressure can be reduced without the fit of the entire shoe made too roomy.

How Poor We Are at Prescribing Diabetic Footwear

According to Medicare's Part B Reimbursement Status (BMAD), the number of pre-fabricated depth shoes fit peaked at 913,213 in 2010 and has been decreasing approximately 10% every year. The latest data available on the APMA website shows that in 2018 there were only 503,063 claims submitted to Medicare for depth shoes.

Some of the decrease in the number of pairs of shoes paid for by Medicare is attributable to growth in Medicare Advantage programs. In 2021, more than 26 million people were enrolled in a Medicare Advantage plan, accounting for 42 percent of the total Medicare population. While these programs are required to provide coverage for diabetic shoes, the number of people getting fit each year is not public information that Medicare publishes each year.[11]

Subjective Obstacles Heard from the Field Contributing to Decreased Medicare Reimbursement for Diabetic Shoes

There's not enough profit to make participation in program worthwhile.

The amount that Medicare pays for fitting shoes and inserts has gone up every year. 2022 allowables are $345.88 for a pair of depth shoes (A5500) with three pairs of prefabricated, heat molded inserts (A5512) and $439.60 for a pair of depth shoes (A5500) with three pairs of custom molded inserts (A5514). Depending on the cost of shoes and inserts, the Medicare fee schedule offers profits of $250 to $350, per patient, per year.

Medicare compliance requirements are too onerous and confusing.

The Medicare program promotes a team approach to care by requiring patients to have a physician who manages

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the diabetes, a physician who cares for the feet, and an expert in shoe fitting to provide shoes and inserts. When podiatrists determine there is a risk factor for ulceration like decreased circulation, decreased feeling, or a structural deformity, it's necessary that the objective findings be shared with the physician managing the patient's diabetes. It's this requirement for sharing exam findings that often creates a logistical hurdle for ensuring the requirements for compliance documentation are met. Medicare makes all the requirements for compliance documentation clear and has agencies charged with ensuring that patient eligibility and compliance documentation requirements are met. These agencies have the right to deny payment when compliance requirements are not met. This sort of oversight is no different than exists for any other category of Medicare payment.

The podiatric foot exam findings should be sent to the certifying physician, along with the Certifying Statement, with instructions to the MD/DO to sign, date, and return, indicating their agreement and that they will keep a copy of the findings in their patient chart.

It's difficult to comply with Medicare requirements when patients are seen only by an NP or PA, not an MD/DO.

The rules for the Medicare shoe program were created at a time when there was much lower utilization of NPs and PAs. Medicare rules are specific regarding the need for an MD or DO to certify that they are managing the patient's diabetes and to sign the required forms. It is sometimes best if the required d documentation is given to the patient with instruction to obtain the necessary signature from the MD/DO.

Lack of adequate awareness on the part of patients who are eligible for new shoes and inserts each calendar year.

Patients will become more excited about and look forward to getting fit with new shoes each year if the benefits are associated with improved independence and mobility. Patients are less interested in learning about their shoes than what their shoes can do for them.

Lack of consistency in-office to include assessment of shoe wear and prescription for replacement on an annual basis.

Medicare's Merit Based Incentive Program (MIPS) includes two quality measures, 126 and 127, that require annual evaluation of patients' footwear and ulcerative risk categorization. This program creates a maximum payment adjustment of +/– 9%.

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Lack of proficiency in being able to educate patients effectively enough about the importance of wearing shoes whenever weight-bearing in order to reduce ground-reactive forces.

Some shoe manufacturers and professional organizations offer Therapeutic Shoe Fitter certification. This short program offers medical assistants a way to become both trained in and credentialed in shoe fitting.

Lack of sufficient staffing or space in the office to accommodate effective shoe fitting.

Medicare reimbursement easily covers the cost of an associate to work with the DPM to ensure that patients are fit efficiently and expertly. Typically, the amount earned in a hour can cover the cost of an associate for a day.

Many More Patients Could Be Helped If We Overcame These Obstacles

Since Medicare coverage for therapeutic shoes began, the number of people 65 and over has increased from 33 million to 56 million.[12] Approximately 20% (21.4%) of adults age ≥65 years have a known diagnosis of diabetes. This means that there are over 10 million people 65 and over in the U.S. with a known diagnosis of diabetes. As nearly half of these people are enrolled in Medicare Advantage plans, it means that less than 10% of people with Medicare who have diabetes and can be fit with shoes are getting them. As only approximately 500,000 with Medicare received shoes in 2018, there are probably today over five million Medicare beneficiaries who would benefit from shoes, covered by Medicare, who are not being fit each year.

Ways Podiatrists Can Promote Diabetic Shoe Fitting

According to the International Working Group on the Diabetic Foot (IWGDF), all people with diabetes should undergo at least a yearly ulcerative risk foot evaluation. Shoe style recommendations should be based on at least annual ulcerative foot risk classification. Shoe style should meet the specific foot risk needs of individuals with diabetes. Diabetic foot exams should include:

Screening for Peripheral Neuropathy

- 10 g monofilament sensitivity;
- Vibration perception;
- Neuropathy disability score

Peripheral Artery Disease

- Palpation of peripheral pulses;
- Ankle-brachial pressure index; toe-brachial pressure index

Evaluation of Foot Structure

- Six-point scale scoring small muscle wasting,
- Charcot foot deformity,
- Bony prominence,
- Prominent metatarsal head,
- Hammer or claw toes
- Limited joint mobility

Assessment of a history of foot ulcer(s) or lower-extremity amputation.[13]

Ulcerative Risk Assessment Grading

Low Risk:

No peripheral neuropathy, no peripheral artery disease, no foot deformity, no previous foot ulcer, no history of lower extremity amputation

Intermediate Risk:

One risk factor on foot screening; either peripheral neuropathy, or peripheral artery disease, or foot deformity,

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and no previous foot ulcer, and no history of lower extremity amputation

High Risk:

Two or more risk factors on foot screening; either peripheral neuropathy, or peripheral artery disease, or foot deformity, with previous foot ulcer, or with history of lower extremity amputation.

Frequency of Evaluation

People with an intermediate- or high-risk foot status:

- Evaluate at least once every three to six months
- Screen for peripheral neuropathy (10 g monofilament sensitivity; vibration perception; neuropathy disability score),
- Peripheral artery disease (palpation of peripheral pulses; ankle-brachial pressure index; toe-brachial pressure index),
- Foot deformity (six point scale scoring small muscle wasting; Charcot foot deformity, bony prominence, prominent metatarsal head, hammer or claw toes and limited joint mobility),
- Assessment of a history of foot ulcer(s) or lower-extremity amputation.[13]

Australian Program with Description of How to Improve Diabetic Shoe Wearing

In 2018, the Australian Diabetes Foot Network revised its guidelines on the provision of footwear for people with diabetes. The guidelines incorporate common findings from all recent systematic reviews on footwear interventions for people with diabetes and recent randomized controlled trials to create 10 key recommendations to guide health professionals managing people with diabetes, choosing the most appropriate footwear for the person's specific foot risk needs.[14]

Footwear recommendations for all people with diabetes at risk of foot ulceration

- Wear footwear that fits, protects, and accommodates the shape of the feet
- Always wear socks within their footwear to reduce shear and friction
- Educate people with diabetes, their relatives and caregivers on the importance of wearing appropriate footwear to prevent ulceration.

Footwear recommendations for people with diabetes at intermediate or high risk of foot ulceration

- Obtain footwear from an appropriately trained professional to ensure it fits and accommodates the shape of their feet.
- Motivate people (or their relatives and caregivers) to check their:

—Footwear, each time before wearing, to ensure there are no foreign objects in the footwear, or penetrating the soles

—Feet, each time their footwear is removed, to ensure there are no signs of abnormal pressure, trauma or ulceration.

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- For people with a foot deformity or pre-ulcerative lesion, consider prescribing medical grade footwear, which may include custom-made insoles
- For people with a healed foot ulcer, prescribe medical grade footwear with custom-made in-shoe insoles with a demonstrated plantar pressure reducing effect at the high-risk areas.
- Review prescribed footwear every three months to ensure it still fits, protects, and supports the foot.

Footwear recommendations for people with diabetes with foot ulceration:

- Footwear is not recommended for treatment
- Prescribe appropriate offloading devices to heal these ulcers.

Suggested Roles and Responsibilities for DPMs to Fit Patients with Shoes That Reduce Ulceration (and Generate Substantial Practice Revenue)

Combining shoe-fitting with ulcerative risk assessment and the benefits of therapeutic shoes offers the greatest convenience for the patient and revenue opportunity for the practice. Dispensing one pair of shoes with inserts each day will result in over $50K of net revenue to the practice from shoes and inserts only. Practices that do not have adequate staff coverage to implement such a routine should consider that the revenue opportunity of fitting a pair a day requires, at most, an hour; shoe revenue earned in that hour could offset the cost of an additional person who could be available for the bulk of the day to assume other responsibilities.

Diabetic Foot Evaluation, Shoe Fitting: Roles and Responsibilities of the DPM

- Performs diabetic foot evaluation on all patients with diabetes
- Prescribes shoes/insoles when increased risk of ulceration is present,
- Supervises dispensing of shoes/insoles.

Front Office Person

- Schedules patients with Medicare, diabetes, and history of ulceration for dedicated diabetic foot evaluation appointment with DPM.

Fitting Person

- Works under the direct supervision of the DPM to select shoes that are therapeutically appropriate and aesthetically acceptable fits
- Completes Medicare compliance documentation based on diabetic foot exam
- Dispenses diabetic shoes.

Alternatives for DPMs If They Prefer to Prescribe Shoes, But Not Fit Shoes that Reduce Ulceration

Employ Your Own Pedorthist

DPM offices can benefit by contracting with a routinely scheduled pedorthist to fit patients prescribed

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shoes. As an independent contractor, working for the DPM, the pedorthist can work under general supervision, meaning that the DPM need not be present when the pedorthist is fitting patients.

Refer to a Local Pedorthist

The best way to ensure good shoe fit is to have a fitting inventory of shoes which patients can try on with appropriate socks and accommodative insoles. Some pedorthists work within shoe stores that have extensive fitting inventory; others work in more of a clinical setting, where a more limited assortment of try-on shoes may be available. It's advantageous when the fitter has the ability to make minor adjustments to shoes and insoles at the time of dispensing.

Refer to Therapeutic Shoe Fitting Service

There are a number of companies that employ contracted pedorthists and therapeutic shoe fitters who fill prescriptions for patients requiring shoes and inserts. An advantage of such an approach is that patients can often be seen at their home, at their convenience. A disadvantage may be a lack of fitting inventory and style selection.

Summary

The number of people with diabetes who need to be expertly fit with therapeutic footwear and inserts has increased significantly since Medicare first provided coverage in 1993. While there has been a significant decrease in the number of shoes paid for by Medicare, there are many resources available for patients to get the care they require.

Almost all podiatry practices treat a significant number of patients with diabetes, yet relatively few annually fit all the patients they can with shoes that can improve mobility, reduce the effects of obesity, and lessen the chance of ulceration and amputation.

Resources are available to make shoe fitting and compliance documentation procurement easier. There are also numerous ways for patients to get shoes prescribed by their podiatrist if the practice decides that it works best to refer patients out. The most important role of the podiatrist is to ensure that patients with diabetes are provided at least annual risk assessment and prescribed footwear and inserts that provide an appropriate level of protection. Also critical is that the podiatrist ensures that whether the shoes are provided within or outside the practice, they are worn whenever the patient is weight-bearing, and that both the patient and caregivers adhere to the strict wearing requirements. Lastly, DPMs should use the directive that shoes and inserts should be replaced as soon as they demonstrate a loss of their protective capability. **PM**

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