

Understanding and Accessing Medicare's Therapeutic Shoes for Persons With Diabetes Benefit

With a diabetes prevalence rate of 1 in 10 Americans, the issue of preventing diabetic foot complications simply cannot be overlooked. Furthermore, due to an aging population that is more likely to develop type 2 diabetes, increases in high-risk minority populations, and the fact that people with diabetes are living longer, the Centers for Disease Control and Prevention expects the prevalence to triple by the year 2050.

While diagnosed diabetes has increased, the number of leg and foot amputations among Americans aged 40 and older with diabetes decreased by 65% between 1996 and 2008. It's important to note that this is about the same time that Medicare began paying for blood glucose monitoring supplies. The rate of amputations unrelated to diabetes remained flat during the same time period.

Foot Ulcers and Amputations

As it stands now, osteomyelitis secondary to an infected, slow-to-heal diabetic foot ulcer is far and away the leading cause of lower extremity amputations in the United States. These amputation-causing wounds typically occur once a person has developed peripheral neuropathy and no longer has normal protective sensation in their feet. Research shows that 60% to 70% of people with diabetes will develop at least some degree of peripheral neuropathy and that 15% can expect to develop a foot ulcer at some point. Unfortunately, as many as 24% of people who develop a foot ulcer will go on to have an amputation.

Diabetes-related lower extremity ulcers and amputations are devastating to the well-being of the patient and are an incredibly taxing financial burden on the health care system. According to the International Diabetes Federation, "In western countries, the economic cost of a diabetic foot ulcer is thought to be between US \$7,000 and

US \$10,000. Where healing is complicated and amputation required, this cost may increase to as much as US \$65,000 per person."

It has been demonstrated in multiple clinical studies that the use of properly selected and fitted therapeutic shoes and custom-made foot orthoses can go a long way toward preventing these horrible complications.

Medicare Coverage for Therapeutic Shoes

Historically, Medicare did not allow payment for shoes or foot orthoses unless they were an integral component of a brace. That exclusion was altered when Congress approved the Therapeutic Shoes for Persons With Diabetes Benefit (TSD) as part of the Omnibus Budget Reconciliation Act of 1987.

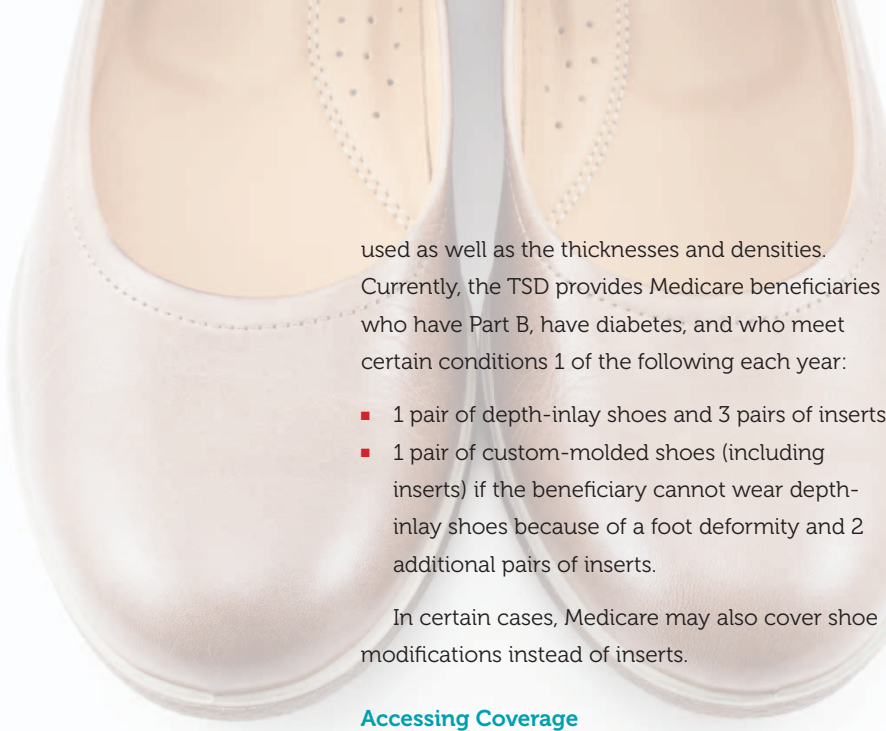
TSD allows for the provision of shoes and foot orthoses for people with diabetes who are Medicare beneficiaries and are at risk of foot complications. The original language of the law specifies that "the footwear . . . be fitted and furnished by a podiatrist, or other qualified individual such as a pedorthist, orthotist or prosthetist." A Certified Therapeutic Shoe Fitter is considered a qualified provider for the TSD benefit. Certification requires the completion of a course approved by the National Commission on Orthotic and Prosthetic Education (16-18 hours of lecture and hands-on education) as well as 250 hours of shoe fitting and insert experience.

There are many companies that specialize in supplying and servicing the TSD/Diabetes patients through a network of dealers. Also, many pedorthists, orthotists, and podiatrists are suppliers for the TSD program.

Over the years, the definition of what constitutes a TSD-covered foot orthoses has changed dramatically to include very specific guidelines pertaining to what materials may be



DENNIS JANISSE, CPED



used as well as the thicknesses and densities. Currently, the TSD provides Medicare beneficiaries who have Part B, have diabetes, and who meet certain conditions 1 of the following each year:

- 1 pair of depth-inlay shoes and 3 pairs of inserts
- 1 pair of custom-molded shoes (including inserts) if the beneficiary cannot wear depth-inlay shoes because of a foot deformity and 2 additional pairs of inserts.

In certain cases, Medicare may also cover shoe modifications instead of inserts.

Accessing Coverage

In order for Medicare to pay for the beneficiary's therapeutic shoes, the doctor treating their diabetes must certify that they meet all of the following 3 conditions:

1. They have diabetes.
2. They have at least 1 of the following conditions in 1 or both feet:
 - partial or complete foot amputation
 - past foot ulcers
 - calluses that could lead to foot ulcers
 - nerve damage because of diabetes with signs of problems with calluses
 - poor circulation
 - deformed foot.
3. They are being treated under a comprehensive diabetes care plan and need therapeutic shoes and/or inserts because of diabetes.

The level of documentation required by Medicare is by far the most challenging aspect of providing TSD therapeutic shoes and foot orthoses to beneficiaries with diabetes. In 1993, the only documentation needed was a prescription from a medical doctor or a podiatrist plus a Statement of Certifying Physician (SCP) justifying the need for special shoes. The SCP had to be signed by the physician managing the patient's diabetes.

In addition to a prescription and the SCP, Medicare now requires office notes from the physician that support the need for therapeutic footwear. It can be daunting to obtain complete and proper documentation. While most physicians

undoubtedly care about assisting their patients in every way possible, the bottom line is that they are also very, very busy trying to meet the demands of their practices.

Quite often, if a physician is unfamiliar with Medicare's TSD documentation requirements, the office notes do not meet the standards and are not adequate to justify coverage. Medicare does not allow amended notes to be used, and thus, another office visit and new notes are necessary. As a result, the process can be chronically frustrating for all parties involved—patient, physician, and podiatrist.

In short, the prescription can be signed by a DPM, MD, or DO. An MD or DO has to sign an SCP certifying that the patient has diabetes, and the documentation/progress notes that correspond to the certification document must exist.

In Medicare's Words

The following is a portion of a letter from Medicare to concerned physicians explaining what is required of them (bold type added for emphasis):

Medicare covers therapeutic shoes and inserts for persons with diabetes. This statutory benefit is limited to one pair of shoes and up to three pairs of inserts or shoe modifications per calendar year. However, in order to qualify, the Medicare statute mandates specific coverage and documentation requirements that must be met.

The need for therapeutic shoes must be certified by a physician who is an M.D. or D.O. and who has the primary responsibility for treating the patient's systemic diabetes. This physician must:

1. Document in the patient's medical record that the patient has diabetes; and
2. Certify that the patient is being treated under a comprehensive plan of care for diabetes, and that the patient needs diabetic shoes; and
3. Document in the patient's medical record the presence of one or more of the following conditions:
 - Previous amputation of the other foot, or part of either foot, or

- History of previous foot ulceration of either foot, or
- History of preulcerative calluses of either foot, or
- Peripheral neuropathy and evidence of callus formation of either foot, or
- Foot deformity of either foot, or
- Poor circulation (i.e., small or large vessel arterial insufficiency) in either foot.

A new certification statement, signed and dated by the treating physician, must be provided on a yearly basis in order to obtain a new pair of shoes or inserts.

It is important to note that even though you may complete and sign a form attesting that all of the coverage requirements have been met, there also must be documentation in your records to indicate that you are managing the patient's diabetes and that one of the conditions listed in 3a–3f is present. If requested by the supplier, you must provide copies of those records.



As with all items covered by Medicare, there must be a detailed written order for the items that are provided. The specifics of what is being provided may be entered by the supplier, but the physician must sign and date the order. Signature or date stamps are not acceptable. A new order is required yearly.

Although the requirements listed in 1–3 above must be documented by the M.D. or D.O. who has the primary responsibility for treating the patient's diabetes, the order could be provided by that physician or by a podiatrist,

physician assistant, nurse practitioner, or clinical nurse specialist.

Physicians are reminded that in order for these items to be reimbursed for your patients, the durable medical equipment supplier will need to collect the medical documentation described above. Providing this documentation is in compliance with the Health Insurance Portability and Accountability Act Privacy Rule. Also note that you may not charge the supplier or the beneficiary to provide this information. Please cooperate with the supplier so that they can provide the therapeutic shoes and inserts that are needed by your patient.

Education Is Key

My hope in penning this article is to help diabetes educators, who play an absolutely vital role in the prevention of diabetes foot complications, understand the process of obtaining therapeutic footwear under Medicare's TSD benefit. In my opinion, the team approach is and always has been the best way to ensure that patients get precisely what they need, when they need it, to maintain good health.

Patient and physician education is the key. Both parties need to understand that the certifying physician (the one providing diabetes management) must perform regular foot exams and document the findings. Without appropriate documentation from the physician, including the certifying statement and supporting notes, the patient will not be eligible for the therapeutic shoe benefit. ■

Dennis Janisse, CPED, is President and CEO of National Pedorthic Services, Inc. and Clinical Assistant Professor, Department of Physical Medicine and Rehabilitation, Medical College of Wisconsin.

RESOURCES

Li Y, et al. Declining rates of hospitalization for nontraumatic lower-extremity amputation in the diabetic population aged 40 years or older: U.S., 1988–2008. *Diabetes Care*. 2013;35:273-277

Viswanathan V, et al. Effectiveness of different types of footwear insoles for the diabetic neuropathic foot: A follow-up study. *Diabetes Care*. 2004;27:474-477