

Does Your Patient Need Diabetic Therapeutic Footwear? (Where Benefit, Evidence, and Bureaucracy Collide)

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In 2012, the estimated incremental burden of diabetic foot ulceration in all Medicare and non-Medicare patients in the United States was \$9.1–13 billion (1). These costs do not include the suffering of patients and families, loss of income, loss of mobility, and predicted increased mortality.

Coverage for extra-depth or custom-molded therapeutic shoes and inserts for individuals with diabetes became a Medicare benefit on 1 May 1993. Within 5 years of the benefit's availability, a report from the Office of the Inspector General of the United States found that 57% of paid claims for therapeutic shoes had missing or inadequate documentation. An audit of beneficiaries found that 3% did not report having diabetes, 12% did not report any of the qualifying conditions, and 47% denied having a foot deformity or previous amputation (2). As with any government program, instances of fraud and abuse have been reported. Dr. Comfort shoes paid a fine of \$27 million for providing inserts that did not meet Medicare standards (3). A provider in California was accused of entering an extended-care facility and offering free shoes to residents, telling them the government wanted them to have shoes. Individuals who did not walk were told the shoes would help them walk (4).

To qualify for footwear coverage, Medicare beneficiaries must have diabetes plus one of the following conditions: neuropathy with evidence of callus, previous or current ulcer,

previous or current pre-ulcerative callus, previous amputation, foot deformities, or poor circulation. How Medicare defines neuropathy (e.g., does it require an insensitve limb?), pre-ulcerative callus, foot deformity, or poor circulation is unclear.

The Centers for Medicare & Medicaid Services requires that the treating physician (MD or DO) must be managing the patient's diabetes under a comprehensive plan of care and must certify that the patient has diabetes and needs therapeutic shoes. Podiatrists, physician's assistants, nurse practitioners, and clinical nurse specialists can write prescriptions for therapeutic footwear. However, certifying physicians must provide documentation that they personally examined a patient's feet or otherwise verify the exam performed by one of these other care providers. This documentation must be kept in the managing physician's patient chart and must be made available to the footwear provider; this practice is sanctioned as a compliant release of information under the federal Health Insurance Portability and Accountability Act.

Scientific evidence regarding the benefit of therapeutic footwear is not clear. A meta-analysis demonstrated that therapeutic footwear was associated with a reduction in amputations in high-risk individuals who had previous ulceration, partial amputation, severe deformity, or Charcot deformity (5). The authors concluded that the studies included in the analysis

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were limited in their ability to determine the benefit of the footwear because of various factors, including inclusion of other interventions such as education, podiatric follow-up, nurse follow-up, and patients' lack of adherence to wearing the footwear. There is no strong evidence of a primary prevention benefit from routine use of therapeutic footwear in individuals with diabetes who have not had previous ulcerations or partial amputations. However, theoretically, preventing even minor trauma to the feet and subsequent ulceration through the use of therapeutic footwear might have benefits. Pecoraro et al. (6) demonstrated a pathway to amputation in which minor trauma causing cutaneous injury preceded amputation in 69 of 80 amputations (86%).

For diabetes care providers, this presents a dilemma. Should we sign every request for therapeutic footwear regardless of the patient's foot status? There are certainly many who cannot afford to pay out-of-pocket for properly fitting footwear. But this would violate the benefit criteria. Is the proper strategy to sign the form for patients who have never had an ulceration or amputation and who have only the most minor deformity irrespective of their neurological or vascular status? Theoretically, this would minimize the risk of skin injuries that result in ulceration. Or, is the proper evidence-based strategy to authorize therapeutic footwear only for patients with previous ulceration, amputation, gross foot deformities, or obviously ischemic limb?

Therapeutic footwear is not a panacea to prevent foot injury and subsequent ulceration or infection leading to amputation. Comprehensive preventive foot care requires multiple levels of intervention, including early and prolonged control of hyperglycemia, hypertension, and hyperlipidemia, as well as smoking cessation.

To reliably and consistently monitor foot conditions, conscientious diabetes care providers routinely

require patients to remove their shoes and socks at every diabetes visit. The preventive examination should be vigilant for dry skin, tinea pedis, calluses, ulcers, deep cracks, long or jagged nails, evidence of footwear abrasion, significant foot deformities, and other abnormalities that could lead to skin trauma. Assessment of patients' neurological status for loss of protective sensation and pulse palpation also helps to identify those who may be at the greatest risk for injury. Referral to an appropriate foot care specialist is urgently coordinated when significant issues are identified.

Patients also need repeated education about the significance of neuropathy and the insidious onset of diabetic neuropathy in particular. Providers should instruct patients to use their eyes and brain to protect their feet from injury because their normal neurological protective sensations may be blunted or absent. Habitual daily foot inspection for signs of injury should be recommended. The habit of inspecting shoes daily for deformities or foreign objects should be encouraged. Regaling them with true stories of patients who have discovered nails, tacks, golf balls, Star Wars toys, and dog food kibble in their shoes will drive home this point. They should know never to walk barefoot, especially outside of the house. Share stories of individuals who burned the soles of their feet off by walking on hot pavement. Remind them that new shoes (including therapeutic footwear) should be broken in gradually to prevent blistering. Tell them about that person who bought new shoes to dance at a relative's wedding, only to get blisters, develop an infection, and wind up with an amputation, never to dance again.

Ideally, diabetes care providers should be the ones initiating the process of obtaining therapeutic shoes for patients who have been identified and who meet the coverage criteria. In reality, however, a significant number of requests for coverage are initiated

by entities that do nothing but sell therapeutic footwear for people with diabetes. Many of these requests are dubious and made on behalf of people who do not have a medical indication for such footwear. These companies do not inform potential beneficiaries that there are specific criteria they need to meet beyond the presence of diabetes. They fax, or instruct patients to fax, blank or half-completed forms to their physician, with the expectation that the doctor will sign off on them.

If the physician's medical record clearly substantiates the criteria for therapeutic footwear, this is relatively painless. But, frequently, the managing physician's notes do not clearly document specific Medicare requirements for footwear coverage, and so certification will require review at a future office visit.

Signing a form without having personally verified the patient's medical need raises a concern for the physician of enabling fraud. Conscientious physicians who refuse to sign such forms when there is no documented qualifying condition are often re-faxed multiple times for footwear requests. This often results in phone calls from angry patients asking why they can't get their free shoes. For a variety of reasons—to save time, yield to an irrational benevolent impulse, or avoid a potential negative physician rating—physicians may be tempted to just sign the forms, using “foot deformity” or “poor circulation” as an indication. After all, who doesn't have a slight bunion or an equivocal pedal pulse?

To prevent futile care and frivolous medical claims, more research is needed to distinguish those individuals who are truly at high risk and likely to benefit from therapeutic footwear from those who are not. Medicare needs to define more clearly what constitutes qualifying neuropathy, significant pre-ulcerative callus, significant foot deformity, and impaired circulation. Reducing such ambiguity might make conflict

among foot care providers, physicians, and beneficiaries less of a problem. Direct marketing of “diabetes footwear” to consumers should be disallowed or at least be required to carry the equivalent of a pharmaceutical product’s “black box” warning explaining that diabetes alone is not a qualifying condition for the benefit. Unfortunately, based on previous government attempts at reducing waste and fraud, the end result likely will be more required documentation and paperwork. This, in turn, will cement our status as “beadles of beadledom,” ensconced behind our computer screens, and further distract us from listening to, examining,

treating, teaching, and strategizing with our patients to improve their diabetes care and overall health.

Duality of Interest

No potential conflicts of interest relevant to this article were reported.

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