

Should Patients Buy Offloading Footwear From You?

It is a challenging, common situation: wound care patients require offloading devices for diabetic and/or neuropathic plantar ulcers, but there is no insurance coverage for those items.



Marc Goldberg

You explain that they will bear the cost of the product(s), but they believe the expenses should be covered by you. When you offer to sell the product(s) directly or suggest the patients purchase them elsewhere, they refuse. Ultimately, their wounds worsen or don't improve. It is well documented that shoe-based offloading approaches are used more frequently than any other modality in the treatment of plantar diabetic foot ulcers (DFUs).^{1,2} It is equally well established that supporting data are limited.³ Additionally, since there is no reimbursement for shoe-based offloading, the products and materials that physicians select to create offloading structures may be based as much on acquisition cost and availability than on any empirical review. When a DFU is the sole indication, the only offloading options that are routinely covered by Medicare (or insurance) are total contact casting and CROW walkers, both of which are used infrequently and are not "accepted" by many physicians or patients.^{1,2} The result of this disconnect between modalities that are reimbursed versus approaches that most physicians use is that there is no broadly recognized standard of care and actual care is highly variable from facility to facility (and even from practitioner to practitioner within one facility).¹

This begs the question: If shoe-based offloading systems are the "default" standard, who should pay? DFUs result in 80,000 lower extremity amputations annually in the United States,⁴ are associated with a five-year mortality rate approaching that of lung cancer,⁵ and cost the U.S. an estimated \$9-13 billion annually.⁶ Given these facts, one might find it surprising that reimbursement exists only for the least utilized offloading approaches.

One might also conclude that this lack of reimbursement may lead to the use of suboptimal offloading systems. With the current uncertainty in the insurance environment, it is unlikely that this issue of reimbursement for shoe-based approaches will resolve anytime soon. So, regardless of whether these systems should be covered by insurance, the operational model for the foreseeable future must be that they are non-covered expenses that will be funded by the patient, absorbed by the physician, or won't be provided.

Shoe modifications with felt or foam and/or postoperative shoes are among the most common DFU offloading approaches. While these modifications may appear easy and to have the lowest cost of materials, consider:

- Demonstrated effectiveness is lacking.³
- Physicians claim to spend 5-10 minutes to make modifications, each time changes are needed. This is time that could be used to see additional patients.
- Offloading structures need frequent replacement, are prone to crushing and/or flattening, and cannot be cleaned if drainage occurs.
- Surgical shoes may alter gait to reduce weight placed on the affected foot, but without conforming insoles they do not offload any specific area of the foot.

After considering the cost of time spent and materials used to make and repeatedly replace the modifications, as well as the lack of positive clinical evidence, modifications with or without postop shoes may be less compelling. Consider: If you are able to charge patients for modifications, could you alternatively charge for a prefabricated device that saves time and may have more evidence? Common reasons for wound care physicians not dispensing offloading footwear and insoles include cost of maintaining inventory and patient resistance. That said, many such products are sold by retailers and can be purchased online (at prices ranging from \$10 for surgical shoes to more than \$300 for CAM Walkers). The existence of a direct-to-consumer marketplace indicates that patients do purchase these devices (despite evidence that people

do not like them) and could purchase them from you, provided they understand the value that you add. So, while you might think it is easier to have patients buy on their own, consider:

- Are you confident that patients will select appropriate products?
- Will your patients properly fit and modify devices as needed?
- Might your patients select devices that are not appropriate for them (eg, creating an unacceptable risk of falling, causing secondary ulcers)?
- Do your patients know what makes one device better than another?

If these devices were available in wound care clinics, concerns such as immediate availability and proper fitting could be addressed.

ECONOMICS OF APPROPRIATE SHOE-BASED OFFLOADING?

Key questions to consider when evaluating the appropriateness of shoe-based offloading systems include: 1) Does the device effectively offload the targeted area without irritating surrounding tissue (such as edge effects) or causing new ulcers in other areas? 2) Will patients tolerate and wear the device? 3) Does the device create an unacceptable risk of falling? 4) Will the device hold up under heavy use, or will it require frequent replacement? 5) Is the device suitable to handle the patient's weight? 6) Can the device be cleaned? 7) Is the device cost effective?

Clinicians who decide to dispense footwear may want to survey online pricing, which will help in discussions with patients as to why an item is appropriate clinically and pricewise. Clinicians may also want to focus on professional products that are unavailable online to avoid patients attempting self-treatment, as well as the inconvenience of explaining why one's price is higher than the discount store's. ■

Marc Goldberg is founder and owner of Bonapeda Enterprises LLC. For a list of references, view this article online: www.todayswoundclinic.com/archive

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Case images courtesy of Payam Rafat, DPM

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'Sub-metatarsal pressure measurements... showed an average pressure reduction of 43.4% when the pixels were removed.' McGuire et al, TUSPM Poster, Presented APMA National Meeting, July 2017

"When indicated, the use of this newly available multi-density insole pressure reduction device, in conjunction with modern wound care techniques, can dramatically reduce the severity of wounds, decrease healing times, and reduce amputation rates."

Rafat et al, Montefiore Mount Vernon Hospital, SAWC Poster, Nov. 2016

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James McGuire DPM, PT, CPed FAPWHc, Clinical Professor, Temple University School of Podiatric Medicine

"In four independent trial sites patients... consistently demonstrated a high level of compliance with the device, and ulcer healing rates appeared comparable to those produced by TCC."

Harry Penny DPM FAPWHc et al, Poster presented at A-DFS Symposium, Venice Italy, Nov. 2017

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