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Advancing foot and ankle medicine and surgery

October 15, 2025

Noridian DME MAC Medical Directors
Jurisdiction A / Jurisdiction D
4510 13th Avenue South
Fargo, ND 58103

CGS DME MAC Medical Directors
Jurisdiction B / Jurisdiction C
26 Century Blvd, Suite ST610
Nashville TN 37214

RE: Increasing Beneficiary Access to Medically Necessary Therapeutic Shoes for Persons with Diabetes

Dear CGS and Noridian DME MAC Medical Directors:

The undersigned organizations request that the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) revise "Therapeutic Shoes for Persons with Diabetes – Policy Article" (A52501) to help restore beneficiary access to this important Medicare benefit. Our organizations represent numerous providers, patients, and suppliers committed to supporting effective management of care for patients with diabetes.

Overview
Over the past decade, there has been a dramatic decrease in beneficiary access to therapeutic shoes for persons with diabetes. This reduced access raises significant concerns as patients with diabetes often develop peripheral neuropathy, which increases the risk for diabetic foot ulceration, infection, and amputation – outcomes that carry tremendous morbidity, mortality, and cost. Therapeutic shoes are effective in preventing these complications, given their extra depth, high toe box, and molded inserts, which protect feet, minimizing friction, and preventing ulcer formation. Despite these benefits, which are well documented in peer-reviewed literature, overly restrictive policies have erected barriers to patients' ability to obtain and utilize therapeutic shoes.

The Problem: Administrative Burden Results in Barriers to Access
Under §1861(s)(12) of the Social Security Act (42 U.S.C. 1395x(s)(12)), Medicare covers diabetic shoes prescribed and furnished by a podiatrist (or other qualified physician) when the physician managing the patient's diabetes documents certain diabetic sequelae and certifies the need for shoes, among other requirements. In the implementation of these requirements, however, the Medicare DME MACs have imposed additional steps that exceed statutory requirements, resulting in significant burden for the providers and suppliers involved in the delivery of the shoes. Specifically, through DME MAC Policy Article A52501, MACs are requiring that the physician managing the diabetes:

> *"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, other M.D or D.O., physician assistant, nurse practitioner, or clinical nurse specialist that is within 6 months prior to delivery of the shoes/inserts …"*

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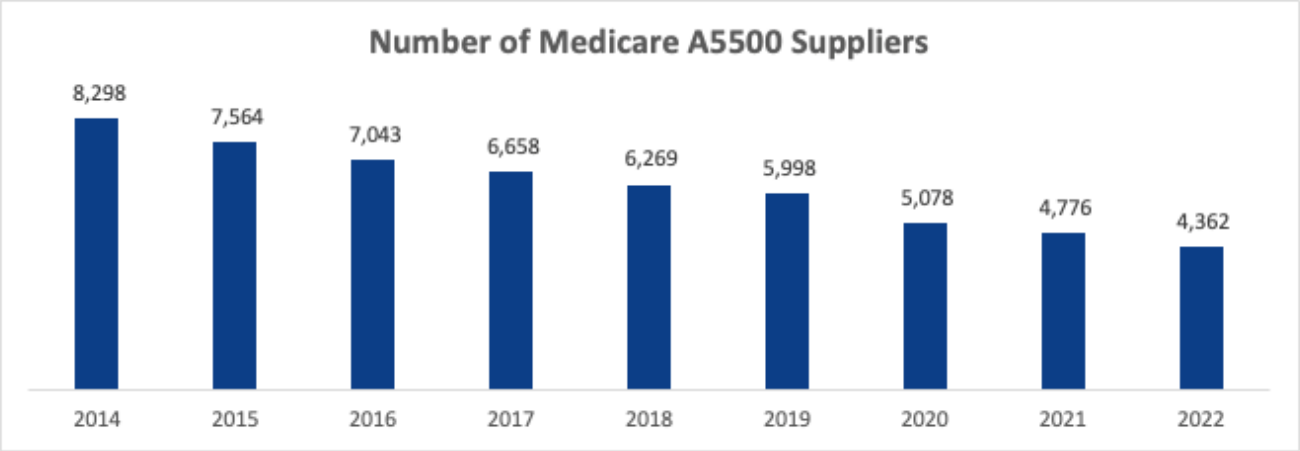
These additional requirements create unnecessary paperwork and burden on the managing physicians, the podiatrists or other practitioner completing the foot assessment, and the shoe suppliers, thereby delaying access to therapeutic shoes for patients who may be at significant risk for ulceration, or worse, preventing patients from ever receiving therapeutic shoes at all. Notably, the signature requirement serves no purpose in furthering patient safety or improving care for patients but rather creates obstacles that prevent patients from receiving the therapeutic shoes they need to support optimal outcomes.

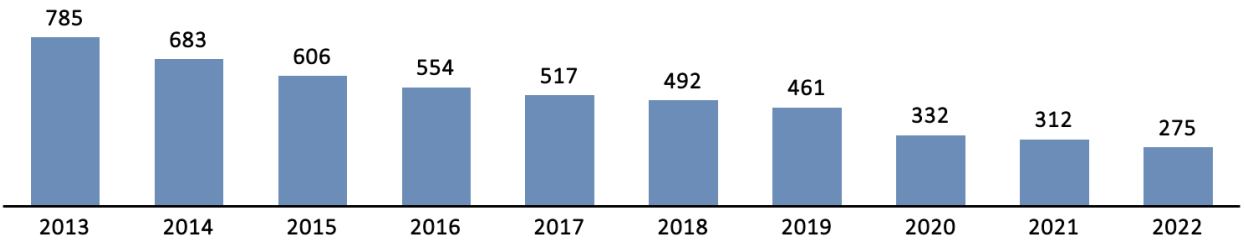
The result of this added burden is decreased access to therapeutic shoes for beneficiaries, which evidence demonstrates can lead to more harmful outcomes and increased foot complications. We provide details below with respect to HCPCS code A5500 (*For diabetics only, fitting (including follow-up), custom preparation and supply of off-the-shelf depth-inlay shoe manufactured to accommodate multi- density insert(s), per shoe).*

To begin, we have heard that many qualified providers have discontinued furnishing therapeutic shoes, leaving patients without access to this critical service. Data on the number of Medicare suppliers of therapeutic shoes (i.e., suppliers of HCPCS code A5500) shown in the table below align with such reports, with the number of suppliers decreasing by almost 50 percent over less than a decade – from 8,298 suppliers in 2014 to 4,362 suppliers in 2022.[1] With fewer therapeutic suppliers available to furnish therapeutic shoes, beneficiaries are sure to have faced increasing difficulty obtaining the shoes they need to protect against ulceration or further complications.



Indeed, Medicare claims data reveal that the number of paid claims for A5500 has declined even more alarmingly over this same period – from roughly 683,000 claims in 2014 to about 275,00 in 2022, as shown in the table below.

[1] Data extracted from CMS. Medicare Durable Medical Equipment, Devices & Supplies – by Supplier and Service. Accessed from https://data.cms.gov/provider-summary-by-type-of-service/medicare-durable-medical-equipment-devices-supplies/medicare-durable-medical-equipment-devices-supplies-by-supplier-and-service on May 20, 2025.



Medicare Submissions of A5500

As the number of beneficiaries receiving this service decreases, the risks of ulcerations, infection, and amputation rise – along with the risks of associated health care costs. The resulting pain, suffering, and early mortality are even more grievous given the potential for prevention that therapeutic shoes offer.

Notably, our members, patients, and partners report that the most common reason their patients do not obtain medically necessary therapeutic shoes is the excessive burden associated with Medicare coverage of this service. In particular, the signature requirement noted above places undue administrative burden on managing physicians, as well as excessive financial risk on suppliers with little clinical benefit. Rather, it creates a check-box requirement that does not advance patient care, given that podiatrists or other qualified physicians have the education, training, and expertise to determine medical necessity of the shoes.

The Evidence: Peer-Reviewed Literature Demonstrates the Benefits of Therapeutic Shoes for Patients with Diabetes

As policy should be rooted in science, we present here an abundance of peer-reviewed literature that supports the benefit of therapeutic shoes for persons with diabetes.

Dahmen et al. note that neuropathy may bring about change in form and function, which can lead to ulceration and deformity, and which often require specially adapted footwear to protect against such complications. The authors discuss therapeutic footwear for the neuropathic foot and notes that protection of the foot is of the greatest importance. The authors note that for the neuropathic foot, the insole must always be custom-made, i.e., pressure reduction must be maximized via full contact with shock absorbing material to create a full-contact surface.[2]

Elftman indicates that a "…patient without protective sensation will not cease ambulating when damage begins to tissues" and, that patients with insensate feet "…require extra-depth shoes with a total-contact accommodative insert to distribute pressure and reduce forces on areas of potential breakdown."[3]

Castro notes that "Once the foot becomes insensate and can no longer feel pain, the risk for ulceration increases substantially." He also notes that "It is well accepted clinically that optimal footwear, which includes extra-depth shoes, custom foot orthoses, and biomechanically appropriate shoe modifications, is an essential element in the treatment of foot ulcers and in the prevention of reulceration of the high-risk diabetic foot."[4]

[2] Dahmen R, Haspels R, Koomen B, Hoeksma AF. Therapeutic footwear for the neuropathic foot: an algorithm. Diabetes Care. 2001 Apr;24(4):705-9. doi: 10.2337/diacare.24.4.705. PMID: 11315835

[3] Elftman, N.W. (2005). Management of the Neuropathic Foot. JPO Journal of Prosthetics and Orthotics, 17, S4-S27

[4] Castro, Ernesto CPed. Pedorthic Management of the Neuropathic Foot. JPO Journal of Prosthetics and Orthotics 17(2):p S32-S34, April 2005.

Lot et al. note that excessive plantar pressure and tissue strain (even from walking) may lead to ulceration in the insensate foot. The researchers investigated the effect of therapeutic footwear and custom-made orthotic inserts on pressure and tissue strain and found that the footwear and orthotic devices tested in their study decreased pressure and soft tissue strain at the second ray of the foot. The authors concluded by sharing that their "…results support the use of therapeutic footwear to help protect the neuropathic foot from injury by decreasing the amount of energy these tissues must absorb during gait."[5]

Robinson et al. note that "…long-term maintenance of the neuropathic foot is often achieved through the use of depth inlay shoes and multi-density accommodative foot orthoses." This type of footwear "…is designed to provide prophylactic protection and long-term management to the at-risk neuropathic population." They also note, "The goal of depth inlay shoes is to provide a total protective environment to the dorsal and plantar aspects of the foot, while allowing adequate internal volume to accommodate off-the-shelf or custom multi-durometer foot orthoses and prevent impingement of the patient's anatomy."[6]

Tang et al. noted that there were significant increases in contact area and significant decreases in peak plantar pressures in areas of the feet in patients with neuropathy when using total contact insoles. While the researchers studied custom made shoes, they also focused on total contact insoles, like the multi- density insoles provided with therapeutic shoes. This study demonstrates that peripheral nerve damage puts patients at risk of deformities and disabilities, such as planar ulceration.[7]

de Jong et al. note that orthopedic footwear improved walking in individuals with hereditary motor sensory neuropathy, especially noting improvement in gait speed and spatiotemporal parameters.[8]

Mrdjenovich notes that therapeutic shoes and custom inserts are an important modality for offloading and prevention, especially with pre-ulcerative skin or the insensate foot at risk of ulcerative breakdown. The author also notes that extra-depth or depth-inlay therapeutic shoes are a necessity for patients with a history of ulceration and / or neuropathy.[9]

Peer-reviewed literature is replete with evidence establishing the efficacy and medical necessity of therapeutic shoes for persons with diabetes. Accordingly, Medicare beneficiaries have access to this important intervention, as outlined under Social Security Act §1861(s)(12)(A). However, the DME MACs have exceeded what is required under Section1861(s)(12)(A) in their requirements for approving coverage of therapeutic shoes in their Policy Article A52501.

The Ask

To address the concerns outlined above, the undersigned organizations ask the DME MACs to remove the following sentence from "Therapeutic Shoes for Persons with Diabetes - Policy Article" (A52501):

[5] Lot DJ, Hastings MK, Commean PK, Smith KE, Mueller MJ. Effect of footwear and orthotic devices on stress reduction and soft tissue strain of the neuropathic foot. Clin Biomech (Bristol, Avon). 2007 Mar;22(3):352-9. doi: 10.1016/j.clinbiomech.2006.10.010. Epub 2006 Dec 19. PMID: 17182156; PMCID: PMC1847616.

[6] Robinson C, Major MJ, Kuffel C, Hines K, Cole P. Orthotic management of the neuropathic foot: an interdisciplinary care perspective. Prosthet Orthot Int. 2015 Feb;39(1):73-81. doi: 10.1177/0309364614545422. PMID: 25614503.

[7] Tang SF, Chen CP, Lin SC, Wu CK, Chen CK, Cheng SP. Reduction of plantar pressures in leprosy patients by using custom made shoes and total contact insoles. Clin Neurol Neurosurg. 2015 Feb;129 Suppl 1:S12-5. doi: 10.1016/S0303- 8467(15)30005-6. PMID: 25683306.

[8] de Jong LAF, Kerkum YL, Altmann VC, Geurts ACH, Keijsers NLW. Effects of orthopedic footwear on postural stability and walking in individuals with Hereditary Motor Sensory Neuropathy. Clin Biomech (Bristol, Avon). 2022 Apr;94:105638. doi: 10.1016/j.clinbiomech.2022.105638. Epub 2022 Mar 31. PMID: 35405625.

[9] Mrdjenovich DE. Off-loading practices for the wounded foot: concepts and choices. J Am Col Certif Wound Spec. 2011 Oct 3;2(4):73-8. doi: 10.1016/j.jcws.2011.02.001. PMID: 24527154; PMCID: PMC3601925.

"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, other M.D or D.O., 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."

Notably, elimination of this duplicative step would not compromise program integrity as a statutory requirement would remain for the managing physician to submit a statement certifying the patient's need for diabetic shoes.

Furthermore, we also highlight that such a change would align with a recent policy that CMS finalized in the Calendar Year (CY) 2025 Physician Fee Schedule (PFS) Final Rule, affecting certification requirements for therapy plans of care with a physician or NPP order. In that final rule, CMS recognized the administrative burden associated with certifying a patient's plan of care (POC) for therapy services, which had included a requirement that a physician or non-physician practitioner (NPP) sign the initial POC with a dated signature or verbal order within 30 days from the first day of treatment, in order for the physical therapist, occupational therapist, or speech language pathologist to be paid for the services. Under CMS' final policy, rather than requiring the physician/NPP signature on the POC, CMS and its contractors are now able to treat a signed and dated physician/NPP therapy order or referral as equivalent to a signature on the POC for the purposes of the initial certification, if the order or referral indicates the type of therapy needed and the written order or referral is on file in the medical record.

Like the original policy that was modified in the CY 2025 PFS Final Rule (requiring a signature on a POC before a therapist can be paid for a service), the coverage requirement for therapeutic shoes – requiring a managing physician to sign a podiatrist's or other physician's medical record notes for certification to be valid – is excessively burdensome and impedes access to care. Our request to eliminate the managing physician's signature requirement, like the final 2025 PFS policy, would eliminate unnecessary burden and remove barriers to care and, in the process, support the delivery of evidence-based foot care for patients with diabetes.

Conclusion and Next Steps

Thank you for your consideration of our comments. We would appreciate a meeting with you to further discuss this problem and the effect our suggested solution would have. To schedule this meeting, please reach out to APMA Vice President of Advocacy Chad Appel, JD, CAE (cappel@apma.org / 301.581.9234).

Sincerely,

American Podiatric Medical Association
Alliance of Wound Care Stakeholders
American Association of Clinical Endocrinologists
American Orthopedic Foot and Ankle Society
American Orthotic & Prosthetic Association
American Public Health Association - Foot and Ankle Health Section
Clinician Task Force
CureLGMD2i
Diabetes Patient Advocacy Coalition
Endocrine Society
National Association for the Advancement of Orthotics and Prosthetics
National Hispanic Medical Association

National Medical Association - Podiatric Medicine and Surgery Section
Pedorthic Footcare Association
Society for Vascular Surgery
Spina Bifida Association
Upperline Health
US Foot & Ankle Specialists

CC:
Kim Brandt, Deputy Administrator and Chief Operating Officer, Centers for Medicare and Medicaid Services
Chris Klomp, Deputy Administrator and Director, Centers for Medicare and Medicaid Services