

Footwear for Persons with Diabetes

In This Session...

- Medicare coverage
- PDAC and What make a shoe a diabetic shoe?
- Risk categories
- Efficacy of therapeutic footwear for persons with diabetes

Medicare

- Footwear for persons with diabetes is often viewed as a “Medicare thing”.
- While Medicare does provide coverage for therapeutic footwear for eligible beneficiaries, all at-risk diabetic feet require proper therapeutic footwear.
- Oftentimes, other third-party payors use Medicare as their model when comes to including or excluding certain items for coverage, but there is no hard and fast rule on this. Verify coverage on every patient (if your practice is one that works with insurances).

Medicare Benefit and Eligibility

- Therapeutic Shoes for Persons with Diabetes (TSPD) benefit
 - Signed into law in 1987, benefit went live in 1993
- Allows coverage for one pair of shoes and three pairs of inserts every *calendar year*.
 - A5500(2) + A5512, A5513 or A5514(6)
 - A5501(2) + A5512, A5513 or A5514(4)
 - Certain shoe modifications may be substituted for inserts

Medicare Benefit and Eligibility

- Patient must have Medicare Part B
- Patient must have diabetes
- Patient must have at least one of six qualifying foot conditions:
 - a) Previous amputation of the other foot, or part of either foot, or
 - b) History of previous foot ulceration of either foot, or
 - c) History of pre-ulcerative calluses of either foot, or
 - d) Peripheral neuropathy with evidence of callus formation of either foot, or
 - e) Foot deformity of either foot, or
 - f) Poor circulation in either foot.

PDAC

- The Pricing, Data Analysis and Coding (PDAC) contractor maintains the Durable Medical Equipment Coding System (DMECS). DMECS is an official source for Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) product code verification and assignment.
- Coding verification is the voluntary process (unless mandated by DME Medicare Administrative Contractor (MAC) policy) that allows manufacturers/distributors to request a coding decision on a DMEPOS item. It is the responsibility of the PDAC to review DMEPOS products to determine the appropriate HCPCS code for Medicare billing. Access the specific Local Coverage Determination (LCD) or Policy
- Coding verification for therapeutic footwear for persons with diabetes is *voluntary*, but keep in mind, if you bill for shoes under the TSPD benefit, the shoes you bill for must meet all PDAC eligibility criteria for A5500.

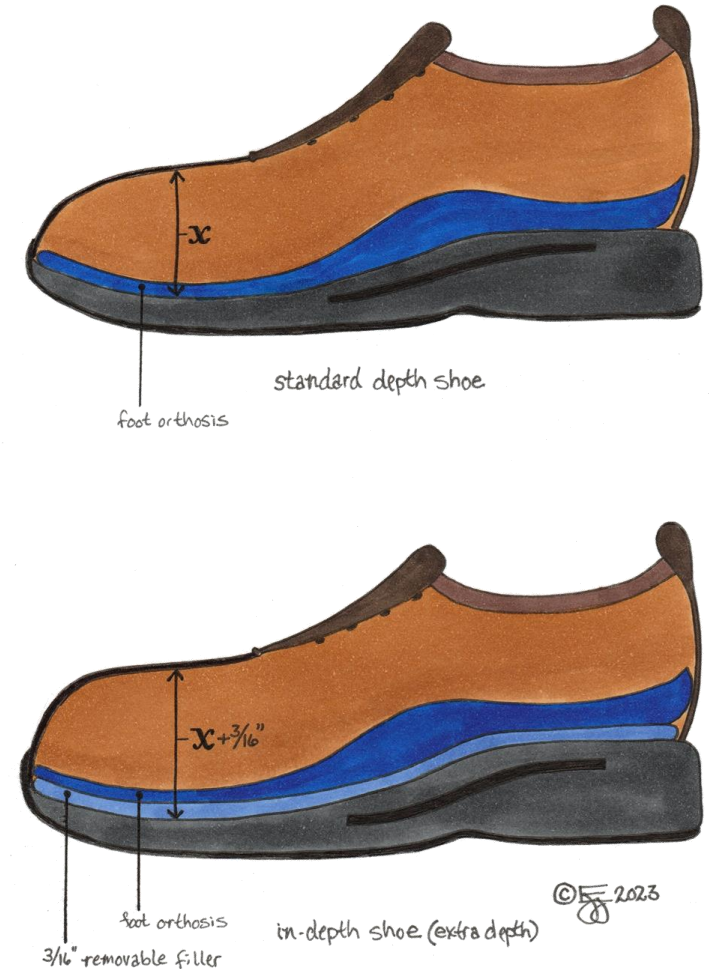
A5500 PDAC Criteria

- Requirements:

- 1.Has a full length, heel-to-toe filler that when removed provides a minimum of 3/16” of additional depth used to accommodate custom-molded or customized inserts; and
- 2.Is made from leather or other suitable material of equal quality; and
- 3.Has some form of shoe closure; and
- 4.Is available in full and half sizes with a minimum of three (3) widths so that the sole is graded to the size and width of the upper portions of the shoe according to the American Standard Last Sizing Schedule or its equivalent. (The American Last Sizing Schedule is the numerical sizing standard used for shoes in the United States.)

A5500 PDAC Criteria

- **Requirement 1:** Has a full length, heel-to-toe filler that when removed provides a minimum of $\frac{3}{16}$ " of additional depth used to accommodate custom-molded or customized insert
 - *Review Criteria:* The three-sixteenths of an inch ($\frac{3}{16}$ ") additional depth requirement is to allow for the extra depth needed in the shoe for the placement of a diabetic insert. The source of the extra depth is derived from the American Last Sizing Schedule used for shoes in the United States. A standard depth shoe that would fit the same patient would not be able to accommodate the protective insert, so extra depth is molded into the shoe. Once the insert is placed into the shoe, there should still be adequate (standard) space for the beneficiary's foot. The presence of this additional depth must be proven in the application, or the shoes will not be assigned code A5500. The method of evidence is up to the submitter.



A5500 PDAC Criteria

- **Requirement 2:** Is made from leather or other suitable material of equal quality
 - *Review Criteria:* “Suitable material” is considered to be leather or leather-like material with a composition capable of providing adequate protection and support for the beneficiary’s foot. Suitable material must exhibit protective qualities comparable to leather, and also water resistance, durability of wear, and ability to hold its form as a leather equivalent shoe. The final configuration of the leather or leather-like material upper must create a toe box and heel counter to provide protection for the toe and heel areas. These are the most common locations for medical foot issues for the diabetic beneficiary and therefore must provide adequate protection. The applicant must present qualitative and/or quantitative information that the material composition of the shoe meets the equivalency characteristics noted above and provides adequate support.



- Leather
- Lycra
- Canvas
- Cotton
- Nylon Mesh
- Wool

A5500 PDAC Criteria

- **Requirement 3:** Has some form of shoe closure
 - *Review Criteria:* As most individuals being appropriately supplied diabetic shoes lack protective sensation in their feet, adequate forms of closure must be present (such as adjustable fastenings or laces) and the shoe must completely envelope the foot. Sandals and open toed shoes do not meet requirements for coding as therapeutic shoes for diabetics. If the foot is exposed to the elements, the risk of ulcers is increased, and the exposure may hamper or prevent adequate treatment of the beneficiary's foot. The closure must be functional and allow for tightening and loosening of the opening to accommodate foot swelling during the day and still provide a good fit and support. This combination of an enveloping shoe and functional closure not only ensures a secure fit that prevents intrusion from small objects, but also reduces shear forces that can lead to worsening of medical condition(s).



A5500 PDAC Criteria

- **Requirement 4:** Is available in full and half sizes with a minimum of three (3) widths so that the sole is graded to the size and width of the upper portions of the shoe according to the American Last Sizing Schedule or its equivalent
 - *Review Criteria:* Manufacturers must be able to demonstrate that their product(s) can accommodate for a broad range of foot shapes to account for the various foot related issues associated with diabetes. As foot swelling is a common issue in many diabetics, the shoes should be available in wide and standard widths to accommodate for this.



Additional Features

- Additional support in medial longitudinal arch
- *Extra*, extra depth
- No prominent internal seams
- Easily modifiable sole
- Outsole designed for stability



Diabetic Foot Risk Categories

Who needs therapeutic shoes?

Category	Category 0	Category 1	Category 2	Category 3
Characteristics	Normal Plantar Sensation	Loss of Protective Sensation (LOPS)	LOPS with either High Pressure or Poor Circulation or Structural Foot Deformities or Onychomycosis	History of Ulceration, Amputation or Neuropathic Fracture
Risk	Low	Moderate	High	Very High
Treatment Plan	Patient education, daily inspection, proper footwear, routine foot care as needed, yearly follow-up. Tight glycemic control necessary to maintain this risk category.	Patient education, proper footwear, soft molded insoles, routine foot care as needed, daily self-inspection, 6 month follow-up	Patient education, proper footwear with possible modifications, custom molded insoles fitted into footwear with possible modification to relieve areas of pressure, scheduled routine foot care, daily self-inspection, 3 month follow-up	Patient education, extra depth footwear with custom modification, custom molded insoles with modifications to relieve pressure, offload with cast as necessary, scheduled routine foot care, daily self-inspection, monthly follow-up

What Does the Research Tell Us?

Do they work?

- Minshall ME, Durden E, Huse DM, McMorrow D, Lidtke RH.
- **Characteristics and Health Care Resource Utilization of Type 2 Diabetes Mellitus (T2DM) Patients Using Therapeutic Footwear.**
- Diabetes, 2014; 63(Suppl. 1): A163.

THERAPEUTIC FOOTWEAR



- Study examined the impact of therapeutic footwear on diabetic complications (foot ulcers and amputations)⁴
- Patients with Type 2 Diabetes mellitus (T2DM)
- Sample size = 26,437
- Followed patients for 1 year before and 2 years after receiving therapeutic shoes

Do they work?

- Igiri BE, Tagang JI, Okoduwa SIR, Adeyi AO, Okeh A.
 - **An integrative review of therapeutic footwear for neuropathic foot due to diabetes mellitus.**
 - Diabetes Metab Syndr. 2019 Mar - Apr;13(2):913-923. doi: 10.1016/j.dsx.2018.12.011. Epub 2018 Dec 21.
 - Systematic review of 125 articles
- Conclusions: The review of the collated literature demonstrated that, therapeutic footwear *can* improve the healing of neuropathic diabetic foot ulcer by redistributing plantar pressure. However, the efficacy of therapeutic footwear requires the inclusion of technical features that should not be compromised from the design to the production of the footwear.
 - The “technical features” they are referring to include:
 - Rocker soles
 - Inserts design based on a model of the patient’s foot
 - Offloading for at-risk sites on the foot

Do they work?

- Bus SA, Valk GD, van Deursen RW, Armstrong DG, Caravaggi C, Hlaváček P, Bakker K, Cavanagh PR.
 - **The effectiveness of footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in diabetes: a systematic review.**
 - Diabetes Metab Res Rev. 2008 May-Jun;24 Suppl 1:S162-80. doi: 10.1002/dmrr.850.
 - Meta-analysis of 129 studies
- Plantar pressure reduction can be achieved by several modalities including casts, walkers, and therapeutic footwear...
 - Evidence shows that therapeutic footwear can successfully prevent ulcers, but the evidence supporting use of footwear for healing ulcers is meager.



Do they work?

- Bus SA, van Deursen RW, Armstrong DG, Lewis JE, Caravaggi CF, Cavanagh PR; International Working Group on the Diabetic Foot.
 - **Footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in patients with diabetes: a systematic review.**
 - Diabetes Metab Res Rev. 2016 Jan;32 Suppl 1:99-118. doi: 10.1002/dmrr.2702.
 - Meta-analysis of 176 studies
- Several randomized controlled trials show the efficacy of therapeutic footwear that demonstrates to relief plantar pressure and is worn by the patient, in the prevention of plantar foot ulcer recurrence.
 - Non-removable offloading is more effective than removable offloading for healing plantar neuropathic forefoot ulcers.
 - Evidence supports the use of non-removable offloading to heal plantar neuropathic forefoot ulcers and therapeutic footwear with demonstrated pressure relief that is worn by the patient to prevent plantar foot ulcer recurrence.

Do they work?

- Bus SA.

Orthopaedic footwear against foot ulcers in diabetes.

Ned Tijdschr
Geneesk.
2014;158:A7497.



- *Orthopaedic footwear that is modified to reduce pressure is not much more effective in preventing foot ulcer recurrence than orthopaedic footwear that did not undergo such modification, unless the shoes are worn as recommended. In that case, the risk of ulcer recurrence is reduced by 46%.*
- In patients with a history of ulceration, compliance in wearing orthopaedic shoes at home is low, while these patients walk more inside the house than outside the house

Do they work?

- Roelof Waaijman, Renske Keukenkamp, Mirjam de Haart, Wojtek P. Polonski, Frans Nollet, and Sicco A. Bus
- **Adherence to Wearing Prescription Custom-Made Footwear in Patients With Diabetes at High Risk for Plantar Foot Ulceration**
- Diabetes Care. 2013 Jun; 36(6): 1613–1618.
- OBJECTIVE: Prescription custom-made footwear can only be effective in preventing diabetic foot ulcers if worn by the patient. We objectively assessed adherence in patients with high risk of ulcer recurrence and evaluated what determines adherence.
- RESEARCH DESIGN AND METHODS: In 107 patients with diabetes, neuropathy, a recently healed plantar foot ulcer, and custom-made footwear, footwear use was measured during 7 consecutive days using a shoe-worn, temperature-based monitor. Daily step count was measured simultaneously using an ankle-worn activity monitor. Patients logged time away from home. Adherence was calculated as the percentage of steps that prescription footwear was worn.
- RESULTS: Mean adherence was 71%. Adherence at home was 61 +/- 32, and away from home 87 ± 26%. In patients with low adherence, adherence at home was 28 ± 24%. Lower BMI, more severe foot deformity, and more appealing footwear were significantly associated with higher adherence.
- CONCLUSIONS: The results show that adherence to wearing custom-made footwear is insufficient, particularly at home where patients exhibit their largest walking activity.

Good Shoes vs Bad Shoes

- Premkumar R, Rajan P, Rima J, Richard J. **Footwear in the causation and prevention of foot ulcers in diabetes mellitus.** Natl Med J India. 2017 Sep-Oct;30(5):255-261.
- **RESULTS** In 1/5 of patients, the primary cause for the FFU was use of inappropriate footwear. The patients used seven different models of footwear, six of which were found to be inappropriate. The straps of footwear caused over 50% of ulcers. 1/3 were due to penetration of sharp objects through the outer sole of footwear; among these cases, 13.6% of ulcers were caused by not using soft inner soles.
- **CONCLUSIONS:**
 - The use of softer insole is least effective in preventing foot ulcers. Similarly, straps contribute to a higher percentage of foot ulcers.
 - Foot ulcers can be prevented by a combination of soft insole, with midsole and hard outsole with proper back counter and adjustable front and back straps.



The compliance dilemma

- Paton JS, Roberts A, Bruce GK, Marsden J. **Patients' Experience of therapeutic footwear whilst living at risk of neuropathic diabetic foot ulceration: an interpretative phenomenological analysis (IPA)**. J Foot Ankle Res. 2014 Feb 22;7(1):16.
- Four overlapping themes that interact to regulate footwear choice emerged from the analyses:
 - a) **Self-perception dilemma**; Resolving the balance of risk between choosing to wear footwear to look and feel normal and choosing footwear to protect their feet from foot ulceration;
 - b) **Reflective adaption**; The modification and individualization of a set of values about footwear usage created in the minds of people with diabetes and neuropathy;
 - c) **Adherence response**; The realignment of footwear choice with personal values, to reinforce the decision not to change behavior or bring about increased footwear adherence, with or without appearance management;
 - d) **Reality appraisal**; A here and now appraisal of the personal benefit of footwear choice on emotional and physical well-being, with additional consideration to the preservation of therapeutic footwear.

The Compliance Dilemma

- Arts ML, de Haart M, Bus SA, Bakker JP, Hacking HG, Nollet F. **Perceived usability and use of custom-made footwear in diabetic patients at high risk for foot ulceration.** J Rehabil Med. 2014 Apr;46(4):357-62.
- **OBJECTIVE:** To assess the perceived usability and use of custom-made footwear in diabetic patients who are at high-risk for foot ulceration, and to elucidate the determinants of usability and use.
- **RESULTS:** Median score for overall appreciation was 8.3 (7.1-9.1).
 - Scores ranged from 6.5 (4.5-8.6) for weight to 9.6 (6.3-9.9) for donning/doffing.
 - Footwear comfort was listed most often (33.3%) as the highest priority.
 - Footwear use was <60% of daytime in 58% of patients.
 - The only significant determinant of footwear use was the perceived benefit of the footwear ($p = 0.045$).
- **CONCLUSION:** Perceived usability of footwear was mostly positive, although individual scores and priorities varied considerably. Footwear use was...dependent only on the perceived benefit of the footwear. Therefore, practitioners should focus on enhancing the patient's appreciation of the therapeutic benefit of [therapeutic] footwear.





Do people with diabetes wear their shoes too small?

- Many patients with diabetes (83%) wear shoes that do not fit, particularly, shoes that are too narrow for their foot width.
- Harrison SJ, et al: Do patients with diabetes wear shoes of the correct size? Int J Clin Pract. 2007 Nov;61(11):1900-4.
- Not really that much worse than the general population. From the diabetic and non-diabetic groups 82% (70/85) and 66% (78/118), respectively wore their shoes either too short or too long.
- McInnes AD, et al: Comparison of shoe-length fit between people with and without diabetic peripheral neuropathy: a case-control study. J Foot Ankle Res. 2012 Apr 16;5(1):9

Shoe Features – Rocker Soles

- **The influence of shoe design on plantar pressures in neuropathic feet.**
- Praet SF, Louwerens JW in Diabetes Care. 2003 Feb;26(2):441-5.
- **CONCLUSIONS:** *The most effective way to offload the forefoot of patients with neuropathic feet is through the use of the rocker sole principle. In general, the effect of an insole depends on the design characteristics of a shoe.*



Shoe Features – Rocker Soles

- Brown D, Wertsch JJ, Harris GF, Klein J, Janisse D. **Effect of rocker soles on plantar pressures.** Arch Phys Med Rehabil. 2004 Jan;85(1):81-6.
- **OBJECTIVE:** To examine the effect of different types of rocker soles on plantar pressures.
- **DESIGN:** In-shoe plantar pressures were measured in subjects without deformity with baseline shoes and 3 types of rockers: toe-only, negative heel, and double.
- **RESULTS:** Significant reduction ($P < .01$) in peak pressure and PTI were recorded across the forefoot for all 3 rockers. The reduction of pressure at the forefoot was balanced by shifting pressure to the midfoot with the negative heel and toe-only rockers.
- **CONCLUSION:** This study lends scientific credence to the prescription of rocker soles for patients who need forefoot pressure reduction, such as in diabetic neuropathy and possible ulceration.



Shoe Features – Rocker Soles

- López-Moral M, Lázaro-Martínez JL, García-Morales E, García-Álvarez Y, Álvaro-Afonso FJ, Molines-Barroso RJ. **Clinical efficacy of therapeutic footwear with a rigid rocker sole in the prevention of recurrence in patients with diabetes mellitus and diabetic polyneuropathy: A randomized clinical trial.** aPLoS One. 2019 Jul 11;14(7):e0219537
- **BACKGROUND:** Therapeutic footwear becomes the first treatment line in the prevention of diabetic foot ulcer and future complications of diabetes. Previous studies and the International Working Group on the Diabetic Foot have described therapeutic footwear as a protective factor to reduce the risk of re-ulceration. In this study, we aimed to analyze the efficacy of a rigid rocker sole to reduce the recurrence rate of plantar ulcers in patients with diabetic foot.
- **PARTICIPANTS AND INTERVENTION:** Fifty-one patients with diabetic neuropathy who had a recently healed plantar ulcer were randomized consecutively into the following two groups: therapeutic footwear with semi-rigid sole (control) or therapeutic footwear with a rigid rocker sole (experimental). All patients included in the study were followed up for 6 months (one visit each 30 ± 2 days) or until the development of a recurrence event.
- **FINDINGS:** A total of 51 patients were randomized to the control and experimental groups. The median follow-up time was 26 [IQR-4.4-26.1] weeks for both groups. On an intention-to-treat basis, 16 (64%) and 6 (23%) patients in the control and experimental groups had ulcer recurrence, respectively. Among the group with >60% adherence to therapeutic footwear, multivariate analysis showed that the rigid rocker sole improved ulcer recurrence-free survival time in diabetes patients with polyneuropathy and DFU history ($P = 0.019$; 95% confidence interval, 0.086-0.807; hazard ratio, 0.263).
- **CONCLUSIONS:** We recommend the use of therapeutic footwear with a rigid rocker sole in patients with diabetes with polyneuropathy and history of diabetic foot ulcer to reduce the risk of plantar ulcer recurrence.

The End