

MEDICAL POLICY

POLICY TITLE	THERAPEUTIC SHOES FOR PERSONS WITH DIABETES
POLICY NUMBER	MP 6.061

Effective Date:	6/1/2022
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[POLICY RATIONALE](#)
[DISCLAIMER](#)
[POLICY HISTORY](#)

[PRODUCT VARIATIONS](#)
[DEFINITIONS](#)
[CODING INFORMATION](#)
[APPENDIX](#)

[DESCRIPTION/BACKGROUND](#)
[BENEFIT VARIATIONS](#)
[REFERENCES](#)

I. POLICY

To be considered medically necessary, an eligible provider must prescribe all orthotics.

Diabetic shoes, supportive devices inserts, and/or modifications to those shoes may be considered **medically necessary** when BOTH of the following criteria are met:

- The patient has diagnosis of diabetes mellitus **and**
- The patient has one (1) 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 pre-ulcerative calluses of either foot; **or**
 - Peripheral neuropathy with evidence of callus formation of either foot; **or**
 - Foot deformity of either foot; **or**
 - Poor circulation in either foot.

For patients meeting the above orthotic criteria, coverage is limited to **ONE** (1) of the following within one (1) calendar year:

- One (1) pair of custom-molded shoes **and** two (2) pairs of inserts; **or**
- One (1) pair of depth shoes **and** three (3) pairs of inserts (not including the non-customized removable inserts provided with such shoes).

If the above criteria are not met diabetic shoes and custom inserts will be denied **as not medically necessary**.

Deluxe Shoe Feature which include but are not limited to style color or type of leather does not contribute to the therapeutic function of the shoe; and therefore is **not medically necessary**.

Items represented by code A5510 reflect compression molding to the beneficiary's foot over time through the heat and pressure generated by wearing a shoe with the insert present. Since these inserts are not considered total contact at the time of dispensing, they do not meet the requirements of the benefit category and will be denied as **not medically necessary** as there is insufficient evidence to support a conclusion supporting the health outcomes or benefits associated with this item.

MEDICAL POLICY

POLICY TITLE	THERAPEUTIC SHOES FOR PERSONS WITH DIABETES
POLICY NUMBER	MP 6.061

NOTE: A modification of a custom-molded or depth shoe will be covered as a substitute for an insert.

The provider requesting/ordering the DME should be a provider with whom the member has established a relationship and is involved in the ongoing care of the member and the condition for which the DME/orthotic is prescribed.

Cross-reference:

MP 6.028 Foot Orthotics and other Podiatric Appliances

II. PRODUCT VARIATIONS

[TOP](#)

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

Note: Coverage for diabetic shoes is mandated by the requirements of Pennsylvania Act 98 of 1998, "Reimbursement of Diabetes Supplies", however, coverage is subject to the terms of the member's contract and annual deductibles and coinsurance.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>

III. DESCRIPTION/BACKGROUND

[TOP](#)

Therapeutic shoes is the term used for shoes that are specially designed and constructed to meet the medical needs of an individual who has specific complications resulting from diabetes. These shoes are available only by a prescription from an eligible professional provider. Therapeutic shoes are either custom-molded or depth-inlay shoes.

IV. DEFINITIONS

[TOP](#)

INSERTS - Medically necessary inserts are those that are total contact, multiple densities, removable inlays that are directly molded to the member's foot or a model of the member's foot and are made of a material suitable for the member's condition.

METATARSAL BARS: These are exterior bars that are placed behind the metatarsal heads in order to remove pressure from the metatarsal heads. The bars are of various shapes, heights, and construction depending on the exact purpose.

OFFSET HEELS: This is a heel flanged at its base either in the middle, to the side, or a combination, that is then extended upward to the shoe in order to stabilize extreme positions of the hind foot.

RIGID ROCKER BOTTOMS: These are exterior elevations with apex positions for 51 % to 75 % distance measured from the back end of the heel. The apex is a narrowed or pointed end of an anatomical structure. The apex must be positioned behind the metatarsal heads and tapering off sharply to the front tip of the sole. Apex height helps to eliminate pressure at the metatarsal

MEDICAL POLICY

POLICY TITLE	THERAPEUTIC SHOES FOR PERSONS WITH DIABETES
POLICY NUMBER	MP 6.061

heads. The steel in the shoe ensures rigidity. The heel of the shoe tapers off in the back in order to cause the heel to strike in the middle of the heel.

ROLLER BOTTOMS (SOLE OR BAR): These are the same as rocker bottoms, but the heel is tapered from the apex to the front tip of the sole.

WEDGES (POSTING): Wedges are either of hind foot, fore foot, or both and may be in the middle or to the side. The function is to shift or transfer weight upon standing or during ambulation to the opposite side for added support, stabilization, equalized weight distribution, or balance.

V. BENEFIT VARIATIONS

[TOP](#)

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VI. DISCLAIMER

[TOP](#)

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VII. CODING INFORMATION

[TOP](#)

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Not Medically Necessary therefore not covered:

HCPCS Code	Description
A5508	For diabetics only, deluxe feature of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe
A5510	For diabetics only, direct formed, compression molded to patient's foot without external heat source, multiple-density insert(s) prefabricated, per shoe

MEDICAL POLICY

POLICY TITLE	THERAPEUTIC SHOES FOR PERSONS WITH DIABETES
POLICY NUMBER	MP 6.061

Medically Necessary:

HCPCS Code	Description
A5500	For diabetics only, fitting (including follow-up), custom preparation and supply of off-the-shelf depth-inlay shoe manufactured to accommodate multidensity insert(s), per shoe
A5501	For diabetics only, fitting (including follow-up), custom preparation and supply of shoe molded from cast(s) of patient's foot (custom molded shoe), per shoe
A5503	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with roller or rigid rocker bottom, per shoe
A5504	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with wedge(s), per shoe
A5505	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with metatarsal bar, per shoe
A5506	For diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe with off-set heel(s), per shoe
A5507	For diabetics only, not otherwise specified modification (including fitting) of off-the-shelf depth-inlay shoe or custom molded shoe, per shoe
A5512	For diabetics only, multiple density insert, direct formed, molded to foot after external heat source of 230 degrees Fahrenheit or higher, total contact with patient's foot, including arch, base layer minimum of 1/4 inch material of shore a 35 durometer or 3/16 inch material of shore a 40 durometer (or higher), prefabricated, each
A5513	For diabetics only, multiple density insert, custom molded from model of patient's foot, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer (or higher), includes arch filler and other shaping material, custom fabricated, each
A5514	For diabetics only, multiple density insert, made by direct carving with cam technology from a rectified cad model created from a digitized scan of the patient, total contact with patient's foot, including arch, base layer minimum of 3/16 inch material of shore a 35 durometer (or higher), includes arch filler and other shaping material, custom fabricated, each

Covered for all diagnosis of diabetes for a medically necessary diabetic orthotic.

E08 – E13; O21.011 - O24.93

VIII. REFERENCES

[TOP](#)

1. *Nordian Healthcare Solutions, LLC (NHS). Therapeutic Shoes for Persons with Diabetes. Local Coverage Determination No. L33369. Durable Medical Equipment Medicare Administrative Carrier Jurisdiction J-A; revised January 1, 2020.*
2. *Pennsylvania (PA) General Assembly. House Bill 401. An act establishing the state board of orthotics, prosthetics, and pedorthotics. [PA General Assembly Web site]. 02/09/05. Available at: <https://www.legis.state.pa.us/CFDOCS/Legis/PN/Public/btCheck.cfm?txtType=HTM&ses>*

MEDICAL POLICY

POLICY TITLE	THERAPEUTIC SHOES FOR PERSONS WITH DIABETES
POLICY NUMBER	MP 6.061

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3. U.S. Department of Health and Human Services, Health Care Financing Administration (HCFA). *Foot care and supportive devices for the feet. Medicare Carriers Manual §2323*. Baltimore, MD: HCFA; 1999.
4. Bus SA, Armstrong DG, van Deursen RW, et al. IWGDF guidance on footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes. *Diabetes Metab Res Rev*. 2016;32 Suppl 1:25-36. doi:10.1002/dmrr.2697
5. Everett E, Mathioudakis N. Update on management of diabetic foot ulcers. *Ann N Y Acad Sci*. 2018;1411(1):153–165. doi:10.1111/nyas.13569
6. American Orthopaedic Foot & Ankle Society (AOFAS). *Shoes and orthotics for diabetics*. [AOFAS Web site]. 2019. Available at: <http://www.aofas.org/footcaremd/conditions/diabetic-foot/Pages/Shoes-and-Orthotics-for-Diabetics.aspx>. Accessed February 3, 2022.

IX. POLICY HISTORY

[TOP](#)

MP 6.061	CAC 9/26/17 New Policy. Diabetic Shoes separated into own policy. Previously addressed in MP 6.028 Orthotics. Coding completed.
	4/1/18 Admin Update. Added new code K0903; effective 4/1/18.
	7/24/18 Consensus review. No change to policy statements.
	1/1/19 Admin Update. Updated new, deleted, and revised HCPCS codes. Diagnosis changed to allow all diabetic diagnosis.
	4/24/19 Consensus review. No change to policy statements.
	4/17/20 Consensus review. No change to policy statements. Coding reviewed. Language revised under Product Variations, Benefit Variations and Disclaimer section.
	9/9/2021 Consensus review. Updated FEP language. No changes to coding. Updated references.
	2/3/2022 Consensus review. No change to policy statement. Reviewed and updated references. No coding changes.

[Top](#)

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