

Subject: Therapeutic Shoes, Inserts or Modifications for Individuals with Diabetes

Guideline #: CG-DME-19

Status: Reviewed

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Last Review Date: 02/15/2024

Description

This document addresses therapeutic shoes, inserts or modifications to therapeutic shoes for people with diabetes. Therapeutic shoes may be custom-molded or depth shoes.

Note: Please see the following for additional information:

- [CG-DME-10 Durable Medical Equipment](#)
- [CG-DME-20 Orthopedic Footwear](#)

Clinical Indications

Medically Necessary:

- I. Therapeutic shoes, inserts or modifications to therapeutic shoes are considered **medically necessary** if the following criteria are met:
 - A. The individual has diabetes mellitus; **and**
 - B. The individual has one or more of the following conditions:
 1. Previous amputation of the other foot or part of either foot; **or**
 2. History of previous foot ulceration of either foot; **or**
 3. History of pre-ulcerative calluses of either foot; **or**
 4. Peripheral neuropathy with loss of protective sensation in the foot and with evidence of callus formation of either foot; **or**
 5. Foot deformity of either foot; **or**
 6. Peripheral vascular disease involving the treated foot; **and**
 - C. The physician who is managing the individual's systemic diabetes condition has certified that indications (A) and (B) above are met and that they are treating the individual under a comprehensive plan of care for their diabetes and that the individual needs therapeutic shoes, inserts or modifications to therapeutic shoes.
- II. A custom-molded shoe is considered **medically necessary** when the individual has a foot deformity that cannot be accommodated by a depth shoe.
- III. A modification of a custom-molded or depth shoe is considered **medically necessary** as a substitute for an insert. Although not intended as a comprehensive list, the following are the most common shoe modifications:
 - A. Rigid rocker bottoms
 - B. Roller bottoms
 - C. Wedges
 - D. Metatarsal bars
 - E. Offset heels

Not Medically Necessary:

Any shoes, shoe inserts or modifications that do not meet the above criteria are considered **not medically necessary**.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS

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
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
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

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 ¼ 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

ICD-10 Diagnosis

E08.00-E08.9	Diabetes mellitus due to underlying condition
E09.00-E09.9	Drug or chemical induced diabetes mellitus
E10.10-E10.9	Type 1 diabetes mellitus
E11.00-E11.9	Type 2 diabetes mellitus
E13.00-E13.9	Other specified diabetes mellitus

When services are Not Medically Necessary:

For the procedure and diagnosis codes listed above when criteria are not met.

Discussion/General Information

Therapeutic footwear is commonly used in clinical practice for preventing and healing foot ulcers in persons with diabetes. Diabetes is a chronic illness in which the body does not properly produce or use insulin. Foot ulcerations, infections, peripheral neuropathy, and lower extremity amputations are common consequences of diabetes. Effective management (including therapeutic shoes, inserts or modifications) of these factors may assist in the prevention of or delay of adverse outcomes. Systematic literature reviews (Bus, 2016b; van Netten, 2016) indicate that sufficient data is available to support the use of therapeutic footwear for the prevention of recurrent foot ulcers in individuals with diabetes; however, additional data is needed related to the prevention of a first foot ulcer.

According to Bus and colleagues (2016a), on behalf of the International Working Group on the Diabetic Foot (IWDF), peripheral neuropathy leads to loss of protective sensation, which is one of the most important risk factors for foot ulcerations in people with diabetes. Loss of protective sensation can result in elevated levels of mechanical pressure, which is a significant contributing factor in the development of diabetic foot ulcers.

The American Diabetes Association (ADA) (2024) does not generally recommend the routine prescription of therapeutic footwear for people with diabetes. However, they do indicate that the use of custom therapeutic footwear can help reduce the risk of future foot ulcers in individuals at high risk. The ADA states, "The use of specialized therapeutic footwear is recommended for people with diabetes at high risk for ulceration, including those with loss of protective sensation, foot deformities, ulcers, callous formation, poor peripheral circulation, or history of amputation." Similar recommendations are made by the Society for Vascular Surgery, the American Podiatric Medical Association, and the Society for Vascular Medicine (Hingorani, 2016).

This document is based on peer-reviewed published literature, Medicare criteria, and current ADA standards.

Definitions

American standard last sizing schedule: The numerical sizing system used for shoes in the United States.

Custom-molded shoe: A shoe that has the following characteristics

- Is constructed over a positive model of the individual's foot
- Is made from leather or other suitable material of equal quality
- Has removable inserts that can be altered or replaced as the individual's condition warrants
- Has some form of shoe closure.

Depth shoe: A shoe that has the following characteristics

- Has a full length, heel-to-toe filler that, when removed, provides a minimum of 3/16 inch of additional depth used to accommodate custom-molded or customized inserts
- Is made from leather or other suitable material of equal quality
- Has some form of shoe closure
- Is available in full and half sizes with a minimum of three 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.

Metatarsal bars: 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 heel: 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: Exterior elevations with apex position 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 taper off sharply to the front tip of the sole. Apex height helps to eliminate pressure at the metatarsal heads. Rigidity is ensured by the steel in the shoe. 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): The same as rocker bottoms except the heel is tapered from the apex to the front tip of the sole.

Therapeutic shoe insert for people with diabetes described by HCPCS code A5512: A total contact, multiple density, prefabricated, removable inlay that is directly molded to the individual's foot or a model of the individual's foot and that is made of a suitable material with regard to the individual's condition. The material responsible for maintaining the shape of the device is called the base layer and must be heat moldable. This material usually constitutes the bottom layer of the device and must be of a sufficient thickness and durometer to maintain its shape during use (at least ¼ inch of Shore A 35 or higher, or 3/16 inch of Shore A 40 or higher). Modifications such as additional arch fill may be necessary to achieve and maintain total contact.

Therapeutic shoe insert for people with diabetes described by HCPCS code A5513: A total contact, custom fabricated, multiple

density, removable inlay that is molded to a model of the individual's foot and that is made of a suitable material with regard to the individual's condition. A custom fabricated device is made from materials that do not have predefined trim lines for heel cup height, arch height and length or toe shape. The base layer of the device must be of a sufficient thickness and durometer to maintain its shape during use (at least 3/16 inch of Shore A 35 material or higher). The base layer is allowed to be thinner in the custom fabricated device because appropriate arch fill or other additional material will be layered up individually to maintain shape and achieve total contact. The central portion of the base layer of the heel may be thinner (but at least 1/16 inch) to allow for greater pressure reduction. The specified thickness of the lateral portions of the base layer must extend from the heel through the distal metatarsals and may be absent at the toes. The top layer of the device may be of a lower durometer and must also be heat moldable.

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

References

Peer Reviewed Publications:

1. Lavery LA, La Fontaine J, Kim PJ. Preventing the first or recurrent ulcers. Med Clin North Am. 2013; 97(5):807-820.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American Diabetes Association. Standards of Medical Care in Diabetes–2024. Diabetes Care 2024; 7(Suppl1):S1-S321.
2. Bus SA, Armstrong DG, van Deursen RW, et al. International Working Group on the Diabetic Foot. IWGDF guidance on footwear and offloading interventions to prevent and heal foot ulcers in patients with diabetes. Diabetes Metab Res Rev. 2016a; 32 Suppl 1:25-36.
3. Bus SA, van Deursen RW, Armstrong DG, et al. International Working Group on the Diabetic Foot (IWGDF). 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. 2016b; 32 Suppl 1:99-118.
4. Evans AM, Rome K, Carroll M, Hawke F. Foot orthoses for treating paediatric flat feet. Cochrane Database Syst Rev. 2022 Jan 26;1(1):CD006311.
5. Hingorani A, LaMuraglia GM, Henke P, et al. The management of diabetic foot: a clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. J Vasc Surg 2016; 63(Suppl.):3S–21S.
6. Lewis J, Lipp A. Pressure-relieving interventions for treating diabetic foot ulcers. Cochrane Database Syst Rev. 2013; (1):CD002302.
7. Medicare Benefit Policy Manual (IOM 100-02). Therapeutic Shoes for Individuals with Diabetes. Chapter 15, Section 140. Rev. 241, 04-01-18. Available at: <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf>. Accessed on February 8, 2024.
8. van Netten JJ, Price PE, Lavery LA, et al. International Working Group on the Diabetic Foot (IWGDF). Prevention of foot ulcers in the at-risk patient with diabetes: a systematic review. Diabetes Metab Res Rev. 2016; 32 Suppl 1:84-98.

Websites for Additional Information

1. American Diabetes Association. Available at: <http://www.diabetes.org/>. Accessed on February 8, 2024.

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History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Description, Discussion, References, and Websites sections.
Reviewed	02/16/2023	MPTAC review. Updated Discussion, Definitions, References, and Websites sections.
Reviewed	02/17/2022	MPTAC review. Updated Discussion, References, and Websites sections.
Reviewed	02/11/2021	MPTAC review. Updated References and Websites sections.
Revised	11/05/2020	MPTAC review. Made minor typographical revisions in Clinical Indications section. Changed 'his/her' to 'their' in Clinical Indications section. Updated Discussion/General Information, Definitions, References, and Websites sections. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review. Discussion/General Information, References, and Websites sections updated.
Reviewed	01/24/2019	MPTAC review. Discussion/General Information, References, and Websites sections updated.
	12/27/2018	Updated Coding section with 01/01/2019 HCPCS updates; added A5514; removed K0903 deleted 12/31/2018.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated formatting in Clinical Indications section. Discussion/General Information, Definitions, and References sections updated. Coding section updated with 04/01/2018 HCPCS changes; added K0903.
Revised	02/02/2017	MPTAC review. Formatting updated in Clinical Indications Section. Medically Necessary statement updated to address peripheral neuropathy with loss of protective sensation and peripheral vascular disease. Discussion and References sections updated.
Reviewed	02/04/2016	MPTAC review. Description, Discussion, References and Definitions sections updated. Removed ICD-9 codes from Coding section.
Revised	02/05/2015	MPTAC review. Medically necessary statements reformatted and clarified. References section updated.

Reviewed	02/13/2014	MPTAC review. Definitions and References sections updated.
Reviewed	02/14/2013	MPTAC review. References section updated.
Reviewed	02/16/2012	MPTAC review. Definitions and References sections updated.
Reviewed	02/17/2011	MPTAC review. Discussion, Definitions, References links and Index updated.
Reviewed	02/25/2010	MPTAC review. Place of service section removed. References updated.
Reviewed	02/26/2009	MPTAC review. References updated.
	10/01/2008	Updated coding section with 10/01/2008 ICD-9 changes.
Reviewed	02/21/2008	MPTAC review. Description, Discussion and References updated. The wording "diabetic shoes" in Medically necessary statement #3 was replaced with "therapeutic shoes, inserts or modifications to therapeutic shoes".
Reviewed	03/08/2007	MPTAC review. References & General Information updated. Coding updated; removed HCPCS A5509, A5511, K0628, K0629 deleted 12/31/2005.
Reviewed	03/23/2006	MPTAC review. Reference added.
New	12/01/2005	MPTAC initial guideline development.
Pre-Merger Organizations		
Anthem, Inc.		No document
Anthem CO/NV	10/29/2004	DME.710 Therapeutic Shoes for Individuals with Diabetes
Anthem CT		Benefit Detail Foot Orthotics
WellPoint Health Networks, Inc.		No document

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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