

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 241	Date: February 2, 2018
	Change Request 10436

SUBJECT: New “K” Code for Therapeutic Shoe Inserts

I. SUMMARY OF CHANGES: To facilitate implementation of this new category of therapeutic shoe inserts, the new code will be added to the Healthcare Common Procedure Coding System (HCPCS) code set effective April 1, 2018. The addition of the code will allow the Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) to correctly adjudicate claims. This recurring update notification applies to Chapter 15 Section 140.

EFFECTIVE DATE: April 1, 2018

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: April 2, 2018

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/140/Therapeutic Shoes for Individual with Diabetes

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

Attachment - Recurring Update Notification

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SUBJECT: New “K” Code for Therapeutic Shoe Inserts

EFFECTIVE DATE: April 1, 2018

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IMPLEMENTATION DATE: April 2, 2018

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) recently revised Appendix C of the Durable Medical, Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards to include a new type of therapeutic shoe insert for individuals with diabetes that is fabricated without molding it to beneficiary-specific physical positive model. The revisions allow the use of direct carving (milling) using a Computer-Aided Design/Computer-Aided Manufacturing (CAD-CAM) or similar system, without the creation of a physical positive model, as a custom fabricated therapeutic shoe insert manufacturing technique falling under the scope of the Therapeutic Shoes Part B benefit.

B. Policy: To facilitate implementation of this new category of therapeutic shoe inserts, the following new code will be added to the HCPCS code set effective April 1, 2018:

K0903 : 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.

The billing jurisdiction for this code is DME MAC.

In addition, the definition of inserts located in Chapter 15, §140, Therapeutic Shoes for Individuals with Diabetes in the Medicare Benefit Policy Manual (Pub. 100-02) is being updated to be consistent with the changes made to the DMEPOS Quality Standards. The Benefit Policy manual language is revised to read as follows:

3 – Inserts

Inserts are total contact, multiple density, removable inlays that are directly molded to the patient's foot or a model of the patient's foot or directly carved from a patient-specific, rectified electronic model and that are made of a suitable material with regard to the patient's condition.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility										
		A/B MAC			D M E M A C	Shared- System Maintainers				Other		
		A	B	H H H		F I S S	M C S	V M S	C W F			
10436.1	<p>The contractors and maintainers shall add the following code to the system for processing:</p> <p>K0903: 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.</p> <p>TOS=J;</p> <p>BETOS = D1F;</p> <p>Pricing = 38;</p> <p>Coverage= C</p> <p>Short Descriptor: Mult den insert direct carv/cam</p>		X		X					X		
10436.2	<p>The Common Working File (CWF) shall add the code to the CWF categories specified below on the HCPC Inquiry (HCPI) file in Health Insurance Master Record (HIMR) in CWF:</p> <p>K0903 : (3,60,62)</p>				X						X	
10436.3	<p>Contractors shall make modifications, if necessary, to load the English descriptions for the new "K" code for Therapeutic Shoe Insert to correctly reflect on any Medicare Summary Notice messaging.</p>		X							X		
10436.4	<p>Contractors shall educate suppliers to use the KX modifier on all claims for K0903 when all requirements in the medical policy have been met.</p>				X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H		
10436.5	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.		X		X	

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Wendy Knarr, Wendy.Knarr@cms.hhs.gov.

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

140 - Therapeutic Shoes for Individuals with Diabetes

(Rev.241, Issued: 02-02-18, Effective: 04-01-18, Implementation: 04-02-18)

Coverage of therapeutic shoes (depth or custom-molded) along with inserts for individuals with diabetes is available as of May 1, 1993. These diabetic shoes are covered if the requirements as specified in this section concerning certification and prescription are fulfilled. In addition, this benefit provides for a pair of diabetic shoes even if only one foot suffers from diabetic foot disease. Each shoe is equally equipped so that the affected limb, as well as the remaining limb, is protected. Claims for therapeutic shoes for diabetics are processed by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs).

Therapeutic shoes for diabetics are not DME and are not considered DME nor orthotics, but a separate category of coverage under Medicare Part B. (See [§1861\(s\)\(12\)](#) and [§1833\(o\)](#) of the Act.)

A. Definitions

The following items may be covered under the diabetic shoe benefit:

1. Custom-Molded Shoes

Custom-molded shoes are shoes that:

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

2. Depth Shoes

Depth shoes are shoes that:

- Have 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;
- Are made from leather or other suitable material of equal quality;
- Have some form of shoe closure; and
- Are 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 shoes according to the American standard last sizing schedule or its equivalent. (The American standard last sizing schedule is the numerical shoe sizing system used for shoes sold in the United States.)

3. Inserts

Inserts are total contact, multiple density, removable inlays that are directly molded to the patient's foot or a model of the patient's foot *or directly carved from a patient-specific, rectified electronic model* and that are made of a suitable material with regard to the patient's condition.

B. Coverage

1. Limitations

For each individual, coverage of the footwear and inserts is limited to one of the following within one calendar year:

- No more than one pair of custom-molded shoes (including inserts provided with such shoes) and two additional pairs of inserts; or
- No more than one pair of depth shoes and three pairs of inserts (not including the noncustomized removable inserts provided with such shoes).

2. Coverage of Diabetic Shoes and Brace

Orthopedic shoes, as stated in the Medicare Claims Processing Manual, Chapter 20, “Durable Medical Equipment, Surgical Dressings and Casts, Orthotics and Artificial Limbs, and Prosthetic Devices,” generally are not covered. This exclusion does not apply to orthopedic shoes that are an integral part of a leg brace. In situations in which an individual qualifies for both diabetic shoes and a leg brace, these items are covered separately. Thus, the diabetic shoes may be covered if the requirements for this section are met, while the brace may be covered if the requirements of [§130](#) are met.

3. Substitution of Modifications for Inserts

An individual may substitute modification(s) of custom-molded or depth shoes instead of obtaining a pair(s) of inserts in any combination. Payment for the modification(s) may not exceed the limit set for the inserts for which the individual is entitled. The following is a list of the most common shoe modifications available, but it is not meant as an exhaustive list of the modifications available for diabetic shoes:

- **Rigid Rocker Bottoms** - These are exterior elevations with apex positions for 51 percent to 75 percent 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 tapered 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)** - These are the same as rocker bottoms, but the heel is tapered from the apex to the front tip of the sole;
- **Metatarsal Bars** - An exterior bar is 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;
- **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 bearing upon standing or during ambulation to the opposite side for added support, stabilization, equalized weight distribution, or balance; and
- **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.

Other modifications to diabetic shoes include, but are not limited to flared heels, Velcro closures, and inserts for missing toes.

4. Separate Inserts

Inserts may be covered and dispensed independently of diabetic shoes if the supplier of the shoes verifies in writing that the patient has appropriate footwear into which the insert can be placed. This footwear must meet the definitions found above for depth shoes and custom-molded shoes.

C. Certification

The need for diabetic shoes must be certified by a physician who is a doctor of medicine or a doctor of osteopathy and who is responsible for diagnosing and treating the patient's diabetic systemic condition through a comprehensive plan of care. This managing physician must:

- Document in the patient's medical record that the patient has diabetes;
- Certify that the patient is being treated under a comprehensive plan of care for diabetes, and that the patient needs diabetic shoes; and
- Document in the patient's record that the patient has one or more of the following conditions:
 - o Peripheral neuropathy with evidence of callus formation;
 - o History of pre-ulcerative calluses;
 - o History of previous ulceration;
 - o Foot deformity;
 - o Previous amputation of the foot or part of the foot; or
 - o Poor circulation.

D. Prescription

Following certification by the physician managing the patient's systemic diabetic condition, a podiatrist or other qualified physician who is knowledgeable in the fitting of diabetic shoes and inserts may prescribe the particular type of footwear necessary.

E. Furnishing Footwear

The footwear must be fitted and furnished by a podiatrist or other qualified individual such as a pedorthist, an orthotist, or a prosthetist. The certifying physician may not furnish the diabetic shoes unless the certifying physician is the only qualified individual in the area. It is left to the discretion of each A/B MAC (B) to determine the meaning of "in the area."