Therapeutic Shoes for Persons with Diabetes

*Adopted from National Government Services website*

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied.

Suppliers are to follow The Health Plan requirements for precertification, as applicable.

Therapeutic shoes require precertification and face to face visit per Affordable Care Act (ACA) guidelines.

Some items in this policy require Pricing Data Analysis, and Coding verification – See The Health Plan fee schedule.

<table>
<thead>
<tr>
<th>CMS National Coverage Policy</th>
<th>Medicare Benefit Policy Manual (IOM 100-02), Chapter 15, Section 140</th>
</tr>
</thead>
<tbody>
<tr>
<td>DME Region LCD Covers</td>
<td>Jurisdiction B-C</td>
</tr>
<tr>
<td>Revision/Review Effective Date</td>
<td>For service performed on or after 01/01/15</td>
</tr>
<tr>
<td></td>
<td><strong>Reviewed/Revised:</strong> 01/01/16, 10/31/13</td>
</tr>
<tr>
<td>The Health Plan</td>
<td>All plans will follow Oversight Region B-C Coverage Determination posted on the CGS website unless otherwise indicated in sections of this policy, contractual agreement or benefit plan document</td>
</tr>
</tbody>
</table>

**DESCRIPTION**

Therapeutic shoes are footwear designed for individuals with foot, heel, ankle and leg problems. They are specially engineered to provide pain relief and support for the ankles and feet of individuals. The primary function of orthopedic shoes is to provide protection to the feet from injury and to effectively manage symptoms of foot disorders, such as diabetes.
COVERAGE GUIDELINES

Therapeutic shoes, inserts, and/or modifications to therapeutic shoes are covered if the following criteria are met:

1. The member has diabetes mellitus; and
2. The member has one or more of the following 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; and
3. The member is being seen by the certifying physician under a comprehensive plan of care for his/her diabetes and that the member needs diabetic shoes, and meets the indications above.
   a. Member must have an in-person visit with the certifying physician and discuss diabetic management and qualifying foot condition within six months of delivery of the shoes.
   b. The certification statement signed on or after the date of the in-person visit and within three months prior to delivery of the shoes and/or inserts.
4. Guidelines under Dispensing Supplies below have been met.

If criteria 1-4 are not met, the therapeutic shoes, inserts, and/or modifications to therapeutic shoes will be denied as noncovered.

Separate inserts may be covered and dispensed independently of diabetic shoes if the supplier of the shoes verifies in writing that the member has appropriate footwear into which the insert can be placed. This footwear must meet the definitions found in this policy for depth shoes or custom-molded shoes.

A custom molded shoe (A5501) is covered when the member has a foot deformity that cannot be accommodated by a depth shoe. The nature and severity of the deformity must be well documented in the supplier’s records and available upon request. If the custom molded shoe is provided, but the medical record does not document why the item is medically necessary, it will be denied as not meeting coverage guidelines.

Shoes are also covered if they are an integral part of a covered leg brace. However, different codes are used for footwear provided under this benefit. See the medical policy on orthopedic footwear for details.

NONCOVERAGE STATEMENT

The Health Plan does not cover refurbishing of foot inserts.

Inserts used in noncovered shoes are noncovered.

Deluxe features of diabetic shoes (A5508) will be denied as noncovered.

There is no separate payment for the fitting of the shoes, inserts or modifications or for the certification of need for prescription of the footwear.
REPAIR AND REPLACEMENT

A new order is not required for the replacement of an insert or modification less than one year from the order on file. The supplier must document the reason for the replacement with the submission of the precertification or claim.

A new order is required for the replacement of any shoe.

A new order is also required for the replacement of an insert or modification more than one year from the most recent order on file. The detailed written order must be signed on or after the date of the visit with the prescribing physician.

An order is not required for a heel or sole replacement or transfer of a shoe to a brace.

CODING INFORMATION

CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.

**HCPCS MODIFIERS**

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EY</td>
<td>NO PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER ORDER FOR THIS ITEM OR SERVICE</td>
</tr>
<tr>
<td>GY</td>
<td>ITEM OR SERVICE STATUTORILY EXCLUDED OR DOES NOT MEET THE DEFINITION OF ANY MEDICARE BENEFIT</td>
</tr>
<tr>
<td>KX</td>
<td>REQUIREMENTS SPECIFIED IN THE MEDICAL POLICY HAVE BEEN MET</td>
</tr>
<tr>
<td>LT</td>
<td>LEFT SIDE</td>
</tr>
<tr>
<td>RT</td>
<td>RIGHT SIDE</td>
</tr>
</tbody>
</table>
# Therapeutic Shoes for Persons with Diabetes

## HCPCS Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>A5500</td>
<td>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.</td>
</tr>
<tr>
<td>A5501</td>
<td>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.</td>
</tr>
<tr>
<td>A5503</td>
<td>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.</td>
</tr>
<tr>
<td>A5504</td>
<td>For Diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with wedge(s), per shoe.</td>
</tr>
<tr>
<td>A5505</td>
<td>For Diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with metatarsal bar, per shoe.</td>
</tr>
<tr>
<td>A5506</td>
<td>For Diabetics only, modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe with off-set heel(s), per shoe.</td>
</tr>
<tr>
<td>A5507</td>
<td>For Diabetics only, not otherwise specified modification (including fitting) of off-the-shelf depth-inlay shoe or custom-molded shoe, per shoe.</td>
</tr>
<tr>
<td>A5508</td>
<td>For Diabetics only, deluxe feature of off-the-shelf depth-inlay shoe or custom-molded shoe, per shoe.</td>
</tr>
<tr>
<td>A5510</td>
<td>For Diabetics only, direct formed, compression molded to patient’s foot without external heat source, multiple-density insert(s) prefabricated, per shoe.</td>
</tr>
<tr>
<td>A5512</td>
<td>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.</td>
</tr>
<tr>
<td>A5513</td>
<td>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.</td>
</tr>
</tbody>
</table>

The presence of an ICD-10 code in this section is not sufficient by itself to assure coverage. Refer to coverage and billing guidelines and documentation requirements for information.

## ICD-10 Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E08.00 - E08.9</td>
<td>Diabetes Mellitus due to underlying condition</td>
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</table>
Diagnoses and ICD-10 codes that support medical necessity are indicated above.

DOCUMENTATION REQUIREMENTS

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports.

This documentation must be available with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
   a. Member’s name
   b. Date
   c. Order must include any specific feature of the base code and every addition requested. The medical record must contain the information that supports the request for each item, and must be submitted with the precertification, if the item requires precertification, or with the claim, if no precertification was required
   d. Order must include diagnosis code
   e. Physician signature with date. Date stamps are not appropriate
2. For custom fabricated items, there must be documentation in the supplier’s records to support the medical necessity of that type of item rather than a prefabricated or over the counter item. The physician order must specifically state “custom orthotic.” For custom fabricated orthoses there must be detailed documentation in the treating physician’s records to support the medical necessity of custom fabricated rather than a prefabricated orthosis. The information from the medical record can then be corroborated by the functional evaluation from the orthotist or prosthetist’s records. This information must be submitted with precertification and or claim.
3. Proof of delivery to be kept on file by the provider of the item.
**Note:** If templates or forms are submitted, (i.e., a Medicare Certificate of Medical Necessity, and/or a provider created form), and all of the required information is not included, The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, home health records.

**Note:** Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

Items listed in this policy that are provided without first obtaining authorization, required per the The Health Plan fee schedule, may be denied for no precertification.

If the prescribing physician is the supplier, a separate order is not required, but the item provided must be clearly noted in the member’s record.

**WHO CAN ORDER DIABETIC SHOES AND INSERTS**

The supplier must obtain a signed statement from the physician who is managing the member’s systemic diabetes condition (i.e., the certifying physician) specifying that the member has diabetes mellitus and has one of conditions listed above in coverage guidelines.

The certifying physician must be an MD or DO.

Podiatrists, physician assistants, nurse practitioners, or clinical nurse specialists are not allowed to sign the "Statement of Certifying Physician for Therapeutic Shoes."

A new certification statement is required each year.

If documentation other than the certifying statement is submitted, the submitted documentation should include:

a. The management of the member’s diabetes; and  
b. How the member met criteria and qualifies for coverage.

A certification statement or an order alone does not meet coverage guidelines.

A podiatrist, orthotist, prosthetist, or pedorthist can determine the appropriate type of footwear (shoes, inserts, and modifications) required. They may also fit and furnish the footwear.

**DIABETIC SHOES PROVIDED WHILE MEMBER IN A PART A COVERED STAY**

Reimbursement for therapeutic shoes provided to a member while the member is covered in a Part A facility is based on specific contract information with the individual facility.

**BILLING GUIDELINES**

Providers are reminded that coding a shoe A5500 or A5501 alone does not indicate that the in person assessment/diagnosis/fitting aspects of the policy have been met.

For members meeting the coverage criteria, coverage is limited to one of the following within one calendar year (January – December):

1. One pair of custom molded shoes (A5501) (which includes inserts provided with these shoes) and two additional pairs of inserts (A5512 or A5513); or
2. One pair of depth shoes (A5500) and three pairs of inserts (A5512 or A5513) (not including the non-customized removable inserts provided with such shoes).

A modification of a custom molded or depth shoe may be covered as a substitute for an insert. Although not intended as a comprehensive list, the following are the most common shoe modifications: rigid rocker bottoms (A5503), roller bottoms (A5503), wedges (A5504), metatarsal bars (A5505), or offset heels (A5506). Other modifications to diabetic shoes (A5507) include, but are not limited to flared heels.

Quantities of shoes, inserts, and/or modifications greater than those listed above will be denied as noncovered.

Codes for inserts or modifications (A5503 – A5508, A5510, A5512, A5513) may only be used for items related to diabetic shoes (A5500, A5501). They must not be used for items related to footwear coded with codes L3215 - L3253. Inserts and modifications used with L coded footwear must be coded using L codes (L3000 - L3649).

When a single shoe, insert or modification is provided, the appropriate modifier, right (RT) or left (LT), must be used. If a pair is provided, report as two units of service on the claim – the RT or LT modifiers should not be used.

Inserts for missing toes or partial foot amputation should be coded L5000 or L5999, whichever is applicable.

For a beneficiary with diabetes missing digit(s) or a forefoot, suppliers have two options for billing inserts:

**Option 1:** For diabetic beneficiaries who do not require the rigidity and support afforded by code L5000 (e.g., beneficiaries missing digits excluding the hallux), suppliers must bill code A5513 for an insert appropriately custom-fabricated to accommodate the missing digit(s). Codes L5000 or A5512 may not be billed in addition to code A5513.

**Option 2:** For beneficiaries missing the hallux or a forefoot that require rigidity and support for effective gait, suppliers must bill L5000 for an insert appropriately custom-fabricated to accommodate the missing digit(s) or forefoot as well as providing the foot-protective functions required for a person with diabetes. Codes A5512 or A5513 may not be billed in addition to code L5000.

**DISPENSING SUPPLIES**

The in person evaluation of the member, by the supplier at the time of selecting the items that will be provided, must include the following:

1. An examination of the member’s feet with a description of the abnormalities that will need to be accommodated by the shoes/inserts modificatiions.
2. Measurements of the member’s feet.
3. Prior to selecting the specific items that will be provided, the supplier must conduct and document an in-person evaluation of the member.
4. The supplier must conduct an in-person evaluation with the member wearing the diabetic shoes and inserts at time of delivery. There must be documentation that the shoes/inserts/modifications fit properly.

Both the supplier’s evaluation and the delivery could occur on the same day depending on items ordered, and if the provider has the appropriate items in stock that meets the member’s needs.

**KX, GA, and GZ MODIFIERS**

Suppliers must add a KX modifier to codes for shoes, inserts, and modification only if criteria 1, 2, and 3 in the coverage guidelines and billing guidelines section of this policy have been met.

If criteria in the coverage guidelines and billing guidelines have not been met, the GY modifier must be added to each code.

**ADVANCED BENEFICIARY NOTICE**

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

**NOTE:** Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

**PRICING, DATA ANALYSIS, AND CODING (PDAC)**

The Health Plan has implemented use of Medicare’s PDAC contractor for review of authorizations. Suppliers should contact the PDAC contractor for guidance on the correct coding of these items. [dmepdac.com/](http://dmepdac.com/)

The only products that may be billed using codes A5512 are those that are specified in the product classification list on the PDAC contractor website.

The two product categories that can be billed with code A5513 are:

1. Inserts custom-fabricated at a central facility and sent to someone other than the member. These items must be listed on the PDAC website.
2. Custom fabricated items that are given to the member by the provider that fabricated the insert. These items do not have to be listed on the PDAC website. However, the provider must provide a list of the materials that were used and a description of the custom fabrication process if requested.

**MEDICARE DEFINITIONS AND DESCRIPTION**

Items represented by code A5510 reflect compression molding to the member’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 noncovered.
The prescribing physician actually writes the order for the therapeutic shoe, modifications and inserts. The prescribing physician may be a podiatrist, MD, or DO. The prescribing physician can be the supplier (i.e., the one who furnishes the footwear).

The supplier is the person or entity that actually furnishes the shoe, modification, and/or insert to the beneficiary and that bills the plan. The supplier may be a podiatrist, pedorthist, orthotist, prosthietist or other qualified individual. The prescribing physician may be the supplier. The certifying physician may only be the supplier if the certifying physician is practicing in a defined rural area or a defined health professional shortage area.

**Depth Shoe (A5500)**

1. Has a full length, heel-to-toe filler that when removed provides a minimum of 3/16 in. of additional depth used to accommodate custom-molded or customized inserts;
2. Made from leather or other suitable material of equal quality;
3. Has some form of shoe closure; and
4. 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.

The American last sizing schedule is the numerical shoe sizing system used for shoes in the United States. This includes a shoe with or without an internally seamless toe.

**Custom Molded Shoe (A5501)**

1. Constructed over a positive model of the member's foot;
2. Made from leather or other suitable material of equal quality;
3. Has removable inserts that can be altered or replaced as the member's condition warrants; and
4. Has some form of shoe closure. This includes a shoe with or without an internally seamless toe.

Code A5512 describes a total contact, multiple density, prefabricated removable inlay that is directly molded to the member’s foot. Direct molded means it has been conformed by molding directly to match the plantar surface of the individual member’s foot. Total contact means it makes and retains actual and continuous physical contact with the weight-bearing portions of the foot, including the arch throughout the standing and walking phases of gait.

The insert must retain its shape during use for the life of the insert. The layer responsible for shape retention is called the “base layer” in the code descriptor. 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 (i.e., at least 3/8 in. of 35 Shore A or higher or at least 3/16 in. of 40 Shore A, or higher). The material responsible for maintaining the shape of the device must be heat moldable. The specified thickness of the base layer must extend from the heel through the distal metatarsals and may be absent at the toes.

Code A5513 describes a total contact, custom fabricated, multiple density, removable inlay that is molded to a model of the member’s foot so that it conforms to the plantar surface and makes total contact with the foot, including the arch. 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 insert must retain its shape during use for the life of the insert. The base layer of the device must be at least 3/16 in. of 35 Shore A or higher material. 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 and accommodate each member’s specific needs. The central portion of the base layer of the heel may be thinner (but at least 1/16 in.) 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. The materials used should be suitable with regards to the member’s condition.

Rigid rocker bottoms (A5503) are exterior elevations with apex position 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 tapering 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) (A5503) are the same as rocker bottoms, but the heel is tapered from the apex to the front tip of the sole.

Wedges (posting) (A5504) 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.

Metatarsal bars (A5505) are exterior bars which 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 (A5506) 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.

A deluxe feature (A5508) does not contribute to the therapeutic function of the shoe. It may include, but is not limited to style, color, or type of leather.

Code A5507 is only to be used for not otherwise specified therapeutic modifications to the shoe or for repairs to a diabetic shoe(s).

With precertification of HCPCS A5507 suppliers must provide a specific/accurate description of the item when billing for any “unlisted procedure code.” Please include manufacturer’s invoice and description of the item.

Deluxe features must be coded using code A5508.

**Toe Fillers and Diabetic Shoe Inserts – Coding Clarification Beneficiaries without Diabetes**

Shoe inserts for beneficiaries with missing toes or partial foot amputations who are not diabetic are considered for coverage under the prosthetic benefit. Code L5000 is described by:

L5000 - Partial foot, shoe insert with longitudinal arch, toe filler
As noted in the descriptor, code L5000 describes a shoe insert with a rigid longitudinal arch support that also incorporates material accommodating the void left by the missing digit(s) or forefoot. Additional soft material is added where contact is made with the residual limb/toes. For beneficiaries missing digits, particularly the hallux (great toe), or the forefoot, L5000 inserts are designed to provide standing balance and toe off support for improved gait. The biomechanical control required of L5000 differs from the foot-protective function provided by inserts used as part of diabetes management.

For beneficiaries who are non-diabetic and require accommodation of missing foot digit(s) or forefoot, suppliers must only bill code L5000. Codes A5512 and A5513 describe inserts used with therapeutic shoes provided to persons with diabetes (see below) and must not be billed for nondiabetic beneficiaries.

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**INTERNET LINKS AND SOURCES**


The Health Plan Provider Procedural Manual. Payment Voucher, Section 14, Page 11


American Academy of Podiatric Sports Medicine aapsm.org/articles.html