

LMRP for Therapeutic Shoes for Persons with Diabetes (L11515)**Contractor Information**

Contractor Name	AdminaStar Federal, Inc.
Contractor Number	00635
Contractor Type	DMERC

LMRP Information

LMRP Database ID Number	L11515
LMRP Title	Therapeutic Shoes for Persons with Diabetes
Original Policy Effective Date	For services performed on or after 05/01/1993
Original Policy Ending Date	
Revision Effective Date	For services performed on or after 04/01/2004
Revision Ending Date	
Contractor's Policy Number	TSD
AMA CPT / ADA CDT Copyright Statement	CPT codes, descriptions and other data only are copyright 2003 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply. CDT-4 codes and descriptions are © 2003 American Dental Association. All rights reserved.
CMS National Coverage Policy	None
Primary Geographic Jurisdiction	DC IL IN

	MD MI MN OH VA WI WV
Oversight Region	Region V
CMS Consortium	Midwest
DMERC Region LMRP Covers	Region B
LMRP Description	Therapeutic Shoes for Persons with Diabetes
Indications and Limitations of Coverage and/or Medical Necessity	<p>For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare 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.</p> <p>For an item to be covered by Medicare, a written signed and dated order must be received by the supplier before a claim is submitted to the DMERC. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as noncovered.</p> <p>Therapeutic shoes, inserts and/or modifications to therapeutic shoes are covered if the following criteria are met:</p> <ol style="list-style-type: none"> 1) The patient has diabetes mellitus (ICD-9 diagnosis codes 250.00-250.93); and 2) The patient has one or more of the following conditions: <ol style="list-style-type: none"> 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 certifying physician who is managing the patient's systemic diabetes condition has certified that indications (1) and (2) are met and that he/she is treating the patient under a comprehensive plan of care for his/her diabetes and that the patient needs diabetic shoes.

For patients meeting these 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 2 additional pairs of inserts (K0628 or K0629); or
- 2) One pair of depth shoes (A5500) and 3 pairs of inserts (K0628 or K0629) (not including the non-customized removable inserts provided with such shoes).

Separate 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 in this policy for depth shoes or custom-molded shoes.

Items represented by code A5510 reflect compression molding to the patient'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.

Inserts used in noncovered shoes are noncovered.

A custom molded shoe (A5501) is covered when the patient 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 may be requested by the DMERC. If there is insufficient justification for a custom molded shoe but the general coverage criteria are met, payment will be based on the allowance for the least costly medically appropriate alternative, A5500.

A modification of a custom molded or depth shoe will 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.

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

Shoes, inserts, and/or modifications that are provided to patients who do not meet the coverage criteria will be denied as noncovered. When codes are billed without a KX modifier (see Documentation section), they will be denied as noncovered.

The particular type of footwear (shoes, inserts, modifications) which is necessary must be prescribed by a podiatrist or other qualified physician, knowledgeable in the fitting of diabetic shoes and inserts. The footwear must be fitted and furnished by a podiatrist, or other qualified individual such as a pedorthist, orthotist or prosthetist.

The certifying physician (i.e., the physician who manages the systemic diabetic condition) may not furnish the footwear unless he/she practices in a defined rural area or a defined health professional shortage area. The prescribing physician (podiatrist or other qualified physician) can be the supplier (i.e., the one who furnishes the footwear).

There is no separate payment for the fitting of the shoes, inserts or modifications or for the certification of need or prescription of the footwear. Unrelated evaluation and management services provided by the physician are processed by the local carrier.

CPT/HCPCS Section Medical And Surgical Supplies-Diabetic Shoes

Benefit Category Shoes for Patients with Diabetes

Coverage Topic Therapeutic Shoes

Coding Information

CPT/HCPCS Codes

The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

EY - No physician or other licensed health care provider order for this item or service.

KX - Specific required documentation on file.

LT - Left Side

RT - Right Side

HCPCS CODES:

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

	<p style="text-align: center;">SHOE, PER SHOE</p> <p>A5510 FOR DIABETICS ONLY, DIRECT FORMED, COMPRESSION MOLDED TO PATIENT'S FOOT WITHOUT EXTERNAL HEAT SOURCE, MULTIPLE-DENSITY INSERT(S) PREFABRICATED, PER SHOE</p> <p>K0628 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 (OR HIGHER), PREFABRICATED, EACH</p> <p>K0629 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</p>
<p>ICD-9 Codes that Support Medical Necessity</p>	<p>The presence of an ICD-9 code listed in this section is not sufficient by itself to assure coverage. Refer to the section on "Indications and Limitations of Coverage and/or Medical Necessity" for other coverage criteria and payment information.</p> <p>250.00 - Refer to ICD-9 code book for descriptions of codes 250.93 in this range.</p>
<p>Diagnoses that Support Medical Necessity</p>	<p>Refer to the previous section.</p>
<p>ICD-9 Codes that DO NOT Support Medical Necessity</p>	<p>Not specified.</p>
<p>ICD-9 Codes that</p>	

**DO NOT Support
Medical Necessity
Asterisk
Explanation**

Diagnoses that DO NOT Support Medical Necessity Not specified.

Reasons for Denials Items listed in this policy will be denied as not medically necessary when provided for conditions other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section unless it specifically states in that section that they will be denied as noncovered.

Non-covered ICD-9 Codes

Non-covered Diagnoses All diagnoses that are not specified in the section ICD-9 Codes that Support Medical Necessity.

Coding Guidelines A depth shoe (A5500) is one that 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; 2) is made from leather or other suitable material of equal quality; 3) has some form of shoe closure; and 4) 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. (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.

A custom-molded shoe (A5501) is one that 1) is constructed over a positive model of the patient's foot; 2) is made from leather or other suitable material of equal quality; 3) has removable inserts that can be altered or replaced as the patient's condition warrants; and 4) has some form of shoe closure. This includes a shoe with or without an internally seamless toe.

An insert described by code K0628 is a total contact, multiple density, prefabricated removable inlay that is directly molded to the patient's foot so that it conforms to the plantar surface and

makes total contact with the foot, including the arch. The insert must retain its shape during use for the life of the insert. 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 (e.g., 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. The materials used should be suitable with regards to the patient's condition.

An insert described by code K0629 is a total contact, custom fabricated, multiple density, removable inlay that is molded to a model of the patient's foot so that it conforms to the plantar surface and makes total contact with the foot, including the arch. The insert must retain its shape during use for the life of the insert. 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 bottom layer of the device must be of a sufficient thickness and durometer to maintain its shape during use (e.g., at least 3/16 inch of Shore A 35 material or higher). The bottom layer of the device should have adequate arch fill to maintain shape and achieve total contact. The materials used should be suitable with regards to the patient'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).

Deluxe features must be coded using code A5508.

Codes for inserts or modifications (A5503 – A5510, K0628, K0629) 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 (2) 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.

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these items.

General Information

Documentation Requirements

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider" (42 U.S.C. section 13951(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include 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 to the DMERC upon request.

An order for each item billed must be signed and dated by the prescribing physician, kept on file by the supplier, and made

available to the DMERC upon request. Items billed to the DMERC before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code. If the prescribing physician is the supplier, a separate order is not required, but the item provided must be clearly noted in the patient's record. A new order is not required for the replacement of an insert or modification within one year of the order on file. However, the supplier's records should document the reason for the replacement. 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 supplier must obtain a signed statement from the certifying physician specifying that the patient has diabetes mellitus, has one of conditions 2a-2f listed in the policy, is being treated under a comprehensive plan of care for his/her diabetes, and needs diabetic shoes. The certifying physician must be either a M.D. or D.O. and may not be a podiatrist. The Statement of Certifying Physician for Therapeutic Shoes developed by the DMERC is recommended (whatever form is used must contain all of the elements contained on the attached recommended form). This statement may be completed by the prescribing physician or supplier but must be reviewed for accuracy of the information and signed by the certifying physician to indicate agreement. A new Certification Statement is required for a shoe, insert or modification provided more than one year from the most recent Certification Statement on file.

Suppliers must add a KX modifier to codes only if all of the criteria in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy have been met. If the requirements for the KX modifier are not met, the supplier may submit additional documentation with the claim to justify coverage, but the KX modifier must not be used.

The ICD-9 code that justifies the need for these items must be included on the claim.

If code A5507 is submitted, the claim must contain a narrative description of the modification or feature provided.

The prescribing physician's name and UPIN number must be listed in Blocks 17 and 17a of the HCFA-1500 form or the electronic equivalent.

Refer to the Supplier Manual for more information on documentation requirements.

Appendices**Footnotes****Utilization Guidelines**

Refer to Indications and Limitations of Coverage and/or Medical Necessity.

Other Comments

The Certifying Physician provides the medical care for the beneficiary's diabetic condition. The certifying physician must be an M.D. or D.O., and may not be a podiatrist.

The Prescribing Physician actually writes the order for the therapeutic shoe, modifications and inserts. The prescribing physician may be a podiatrist, M.D., or D.O.

The Supplier is the person or entity that actually furnishes the shoe, modification, and/or insert to the beneficiary and that bills Medicare. The supplier may be a podiatrist, pedorthist, orthotist, prosthetist 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.

Sources of Information and Basis for Decision

Reserved for future use.

Advisory Committee Meeting Notes

Start Date of Comment Period 05/01/1993

End Date of Comment Period 06/14/1993

Start Date of Notice Period 07/01/1993

Revision History Number	003
Revision History Explanation	<p>Revision effective date: 04/01/2004 HCPCS CODES AND MODIFIERS: Added: K0628 and K0629 Deleted: A5509 and A5511 CODING GUIDELINES: Added definitions for codes K0628 and K0629</p> <p>Revision Effective Date: 04/01/2003 POLICY TITLE: Retitled policy to reflect current American Diabetes Association nomenclature. HCPCS CODES AND MODIFIERS: Added: EY INDICATIONS AND LIMITATIONS OF COVERAGE: Added standard language concerning coverage of items without an order. Clarified the term “calendar year” to mean the period from January through December. DOCUMENTATION REQUIREMENTS: Added standard language concerning use of the EY modifier for items without an order.</p> <p>The revision dates listed below are the approximate dates the revisions were published and not necessarily the effective dates for the revisions.</p> <p>03/01/2002 – Crosswalked HCPCS code A5502 to A5509, A5510 and A5511. Added non-coverage statement for A5510. Updated ICD-9 code range for diabetes mellitus in Coverage and Payment Rules section. Added RT and LT modifiers. Replaced ZX with KX modifier. Clarified that code A5507 can be used for repairs to diabetic shoes. Clarified that the certifying physician may not be a podiatrist.</p> <p>12/01/2000 – Revised Statement of Certifying Physician for Therapeutic Shoes form adding “Circle all that apply” for all questions and statement that person signing the form must be an M.D. or D.O.</p> <p>03/01/1998 – Removed HCPCS L3649, added HCPCS K0401. Added definitions for certifying physician, prescribing physician, and supplier in the Definitions section.</p> <p>03/01/1995 – Revised definition of ZX modifier in Documentation section.</p>

**Last Reviewed on
Date**

**Disclaimer
Specialty Name**

LMRP Attachments Physician Statement Therapeutic Shoes

This page intentionally left blank.

Statement of Certifying Physician for Therapeutic Shoes

Patient name: _____

HIC #: _____

I certify that all of the following statements are true:

- 1) This patient has diabetes mellitus.
- 2)
- 3) This patient has one or more of the following conditions. (Circle all that apply):
 - a) History of partial or complete amputation of the foot
 - b) History of previous foot ulceration
 - c) History of pre-ulcerative callus
 - d) Peripheral neuropathy with evidence of callus formation

 - e) Foot deformity
 - f) Poor circulation
- 4) I am treating this patient under a comprehensive plan of care for his/her diabetes.
- 5)
- 6) This patient needs special shoes (depth or custom-molded shoes) because of his/her diabetes.

Physician signature:

Date Signed: _____

Physician name (printed – must be M.D. or D.O.):

Physician address:

Physician UPIN:

This page has been intentionally left blank.