

LCD for Therapeutic Shoes for Persons with Diabetes (L11515)

Contractor Information

Contractor Number

00635

Contractor Type

DMERC

LCD Information

LCD ID Number

L11515

LCD Title

Therapeutic Shoes for Persons with Diabetes

Contractor's Determination Number

TSD

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CMS National Coverage Policy

None

Original Determination Effective Date

For services performed on or after 05/01/1993

Original Determination Ending Date**Revision Effective Date**

For services performed on or after 01/01/2006

Revision Ending Date**Indications and Limitations of Coverage and/or Medical Necessity**

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.

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 not medically necessary.

The statutory coverage criteria for therapeutic shoes are specified in the related Policy Article.

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.

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.

Coverage Topic

Therapeutic Shoes

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

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 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 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

ICD-9 Codes that Support Medical Necessity

Not specified

For ICD-9 codes relating to statutory coverage, see Policy Article.

Diagnoses that Support Medical Necessity

Not specified.

ICD-9 Codes that DO NOT Support Medical Necessity

Not specified.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

Not specified.

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. §1395l (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 an 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. This information does not have to be sent in with the claim but must be substantiated in the patient's medical record and available to the DMERC upon request. If the requirements for the KX modifier are not met, the KX modifier must not be used.

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

Refer to the Supplier Manual for more information on documentation requirements

Appendices

Utilization Guidelines

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

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

005

Revision History Explanation

Revision Effective Date: 01/01/2006 (March 2006 Publication)

HCPCS CODES AND MODIFIERS

Added: A5512 and A5513

Deleted: K0628 and K0629

Revision Effective Date: 01/01/2006 (December 2005 Publication)

LMRP converted to LCD and Policy Article

DOCUMENTATION REQUIREMENTS:

Removed the requirement for additional documentation to be submitted with the claim.

Removed the requirement for a narrative description to be included on a claim with code A5507.

Removed claim form completion reference for the CMS-1500 form or the electronic equivalent.

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

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.

The revision dates listed below are the approximate dates the revisions were published and not necessarily the effective dates for the revisions.

03/01/2002 – Crosswalked HCPCS code A5502 to A5509, A5510 and A5511. Added noncoverage 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.

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.

03/01/1998 – Removed HCPCS L3649, added HCPCS K0401. Added definitions for certifying physician, prescribing physician, and supplier in the Definitions section.

03/01/1995 – Revised definition of ZX modifier in Documentation section.

Last Reviewed On Date

Related Documents

Article(s)

A37273 - Therapeutic Shoes for Persons with Diabetes – Policy Article – Effective January 2006

LCD Attachments

Physician Certification Statement

Other Versions

- Updated on 11/21/2005 with effective dates 01/01/2006 - N/A
- Updated on 12/31/2005 with effective dates 04/01/2004 - 12/31/2005
- Updated on 09/04/2004 with effective dates 04/01/2004 - N/A
- Updated on 02/26/2004 with effective dates 04/01/2004 - N/A
- Updated on 02/18/2003 with effective dates 04/01/2003 - 03/31/2004

Article for Therapeutic Shoes for Persons with Diabetes – Policy Article – Effective January 2006 (A37273)

Contractor Information

Contractor Number

00635

Contractor Type

DMERC

Article Information

Article ID Number

A37273

Article Type

Article

Key Article

Yes

Article Title

Therapeutic Shoes for Persons with Diabetes – Policy Article – Effective January 2006

Original Article Effective Date

01/01/2006

Article Revision Effective Date

01/01/2006

Article Text**NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES**

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

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:

- 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.

If criteria 1, 2 or 3 are not met, the therapeutic shoes, inserts and/or modifications to therapeutic shoes will be denied as noncovered. When codes are billed without a KX modifier (see Documentation section of accompanying Local Coverage Determination), they will be denied as noncovered.

For patients 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 2 additional pairs of inserts (A5512 or A5513); or

2) One pair of depth shoes (A5500) and 3 pairs of inserts (K0628 or K0629) (not including the noncustomized removable inserts provided with such shoes).

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

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.

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 or prescription of the footwear. Unrelated evaluation and management services provided by the physician are processed by the local carrier.

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 provides the medical care for and manages the beneficiary's systemic diabetic condition. The certifying physician must be an M.D. or D.O. and may not be a podiatrist. The certifying physician may not furnish the footwear unless he/she practices in a defined rural area or a defined health professional shortage area.

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 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 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.

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.

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.

Code A5512 describes a total contact, multiple density, prefabricated removable inlay that is directly molded to the patient's foot. Direct molded means it has been conformed by molding directly to match the plantar surface of the individual patient'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 ¼ inch of 35 Shore A or higher or at least 3/16 inch 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 patient'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 inch 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 patient's specific needs. 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. 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 – 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 (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.

For claims with dates of service on or after July 1, 2006, the only products that may be billed to the DMERCs using codes A5512 and A5513 are those for which a Coding Verification Review has been made by the Statistical Analysis DME Regional Carrier (SADMERC) and subsequently published on the appropriate Product Classification List. Information concerning the documentation that must be submitted to the SADMERC for a Coding Verification Review can be found on the SADMERC web site or by contacting the SADMERC. If an insert has not received a written coding verification from the SADMERC or if it is determined that the insert does not meet the criteria for the code, it must be billed with code A9270 (noncovered item).

Coverage Topic

Therapeutic Shoes

Coding Information

ICD-9 Codes that are Covered

The presence of an ICD-9 code listed in this section is not sufficient by itself to assure coverage. Refer to the Article Text field, Non-Medical Necessity Coverage and Payment Rules section for other coverage criteria and payment information.

250.00 DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE II OR UNSPECIFIED TYPE,
- NOT STATED AS UNCONTROLLED - DIABETES WITH UNSPECIFIED COMPLICATION, TYPE I
250.93 [JUVENILE TYPE], UNCONTROLLED

ICD-9 Codes that are Not Covered

All codes not specified in the previous section.

Other Information

Revision History Explanation

Revision Effective Date: 01/01/2006 (March 2006 Publication)

CODING GUIDELINES:

Added: A5512 and A5513

Deleted: K0628 and K0629

Effective for dates of service on or after 07/01/2006

Revised requirements for Coding Verification Review by the SADMERC

Effective Date: 01/01/2006 (December 2005 Publication)

LMRP converted to LCD and Policy Article

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added a statement clarifying Therapeutic Shoes for Persons with Diabetes codes and Orthopedic Footwear codes.

CODING GUIDELINES:

Added requirement for Coding Verification Review by SADMERC for codes A5500, K0628, K0629.

Related Documents

LCD(s)

L11515 - Therapeutic Shoes for Persons with Diabetes

Other Versions

Updated on 11/22/2005 with effective dates 01/01/2006 - N/A

Updated on 11/21/2005 with effective dates N/A - N/A