LCD - Therapeutic Shoes for Persons with Diabetes (L33369)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont
Noridian Healthcare Solutions,	DME MAC	19003 - DME MAC	J-D	Alaska

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES
LLC				American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

LCD Information

Document Information

LCD ID
L33369

LCD Title
Therapeutic Shoes for Persons with Diabetes

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

Original Effective Date
For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 01/01/2020

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
N/A

Notice Period End Date
N/A

CMS National Coverage Policy

Medicare Benefit Policy Manual (IOM 100-02), Chapter 15, Section 140

Coverage Guidance

Coverage Indications, Limitations, 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.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

The statutory coverage criteria for therapeutic shoes including the requirement for an order 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 beneficiary 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 beneficiary 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 a custom molded shoe is provided but the medical record does not document why that item is medically necessary, it will be denied as not reasonable and necessary.

GENERAL

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed Standard Written Order (SWO) before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

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

GA - Waiver of liability statement issued as required by payer policy, individual case

GY - Item or service statutorily excluded or does not meet the definition of any Medicare benefi

GZ - Item or service expected to be denied as not reasonable and necessary

KX - Requirements specified in the medical policy have been met

LT - Left Side

RT - Right Side

HCPCS CODES:

Group 1 Codes: (12 Codes)

CODE	DESCRIPTION
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

CODE	DESCRIPTION
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
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

General Information

Associated 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.” It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner'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 upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- SWO
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

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

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

Miscellaneous

Appendices

Utilization Guidelines
Refer to Coverage Indications, Limitations and/or Medical Necessity

Sources of Information

N/A

Bibliography

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
01/01/2020	R8	Revision Effective Date: 01/01/2020 COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Revised: Order information as a result of Final Rule 1713 CODING INFORMATION: Removed: Field titled "Bill Type" Removed: Field titled "Revenue Codes" Removed: Field titled "ICD-10 Codes that Support Medical Necessity" Removed: Field titled "ICD-10 Codes that DO NOT Support Medical Necessity" Removed: Field titled "Additional ICD-10 Information" GENERAL DOCUMENTATION REQUIREMENTS: Revised: "Prescriptions (orders)" to "SWO" *03/05/2020: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are due to non-discretionary coverage updates reflective of CMS FR-1713.*	• Provider Education/Guidance • Other
01/01/2019	R7	Revision Effective Date: 01/01/2019 HCPCS CODES: Removed: K0903 from Group 1 Codes, per annual HCPCS code release Added: A5514 to Group 1 codes, crosswalk from K0903, per annual HCPCS code release Revised: A5513 code narrative, per annual HCPCS code release	• Revisions Due To CPT/HCPCS Code Changes
04/01/2018	R6	Revision Effective Date: 04/01/2018 HCPCS CODES: Added: K0903 to Group 1 Codes, per quarterly HCPCS code release (effective 04/01/2018) *04/26/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.*	• Revisions Due To CPT/HCPCS Code Changes
01/01/2017	R5	Revision Effective Date: 01/01/2017 COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:	• Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		Removed: Standard Documentation Language Added: New reference language and directions to Standard Documentation Requirements Added: General Requirements DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: General Documentation Requirements Added: New reference language and directions to Standard Documentation Requirements POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: Direction to Standard Documentation Requirements Removed: Supplier Manual reference from Miscellaneous Removed: PIM reference from Appendices RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article	
07/01/2016	R4	Revision Effective Date 07/01/2016 DOCUMENTATION REQUIREMENTS: Revised: Standard documentation language for orders, added New order requirements, and Correct coding instructions; revised Proof of delivery instructions and removed Method 3 as it does not apply – Effective 04/28/16	• Provider Education/Guidance
07/01/2016	R3	Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.	• Change in Assigned States or Affiliated Contract Numbers
10/01/2015	R2	**Revision Effective Date: 10/31/2014** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to add who can enter date of delivery date on the POD Removed: ICD-9 CM reference	• Provider Education/Guidance
10/01/2015	R1	**Revision Effective Date: 02/04/2011 (June 2014 Publication)**	• Typographical Error

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
		COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Detailed written order verbiage regarding reasonable and necessary denial (reference related policy article and PIM 5.2.3).	

Associated Documents

Attachments

Statement of Certifying Physician (10 KB) (Uploaded on 04/27/2018)

Related Local Coverage Documents

Articles

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

A52501 - Therapeutic Shoes for Persons with Diabetes - Policy Article

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
02/28/2020	01/01/2020 - N/A	Currently in Effect (This Version)
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

N/A