

LCD for Speech Generating Devices (L11534)

Contractor Information

Contractor Name

[NHIC, Corp.](#)

Contractor Number

16003

Contractor Type

DME MAC

LCD Information

LCD ID Number

L11534

LCD Title

Speech Generating Devices

Contractor's Determination Number

SGD

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CMS National Coverage Policy

CMS Pub. 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Section 50.1, 280.1

Primary Geographic Jurisdiction

Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

LCD Information

Oversight Region

Region I

DME Region LCD Covers

Jurisdiction A

Original Determination Effective Date

For services performed on or after 07/01/2001

Original Determination Ending Date

Revision Effective Date

For services performed on or after 12/01/2009

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. 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.

A speech generating device (SGD) (E2500 - E2511) is covered when all of the following criteria (1-7) are met:

1. Prior to the delivery of the SGD, the patient has had a formal evaluation of their cognitive and communication abilities by a speech-language pathologist (SLP). The formal, written evaluation must include, at a minimum, the following elements:
 - a. Current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of the impairment;
 - b. An assessment of whether the individual's daily communication needs could be met using other natural modes of communication;
 - c. A description of the functional communication goals expected to be achieved and treatment options;

LCD Information

- d. Rationale for selection of a specific device and any accessories;
 - e. Demonstration that the patient possesses a treatment plan that includes a training schedule for the selected device;
 - f. The cognitive and physical abilities to effectively use the selected device and any accessories to communicate;
 - g. For a subsequent upgrade to a previously issued SGD, information regarding the functional benefit to the patient of the upgrade compared to the initially provided SGD; and
2. The patient's medical condition is one resulting in a severe expressive speech impairment; and
 3. The patient's speaking needs cannot be met using natural communication methods; and
 4. Other forms of treatment have been considered and ruled out; and
 5. The patient's speech impairment will benefit from the device ordered; and
 6. A copy of the SLP's written evaluation and recommendation have been forwarded to the patient's treating physician prior to ordering the device; and
 7. The SLP performing the patient evaluation may not be an employee of or have a financial relationship with the supplier of the SGD.

If one or more of the SGD coverage criteria 1-7 is not met, the SGD will be denied as not medically necessary.

Codes E2500 - E2511 perform the same essential function - speech generation. Therefore, claims for more than one SGD will be denied as not medically necessary.

ACCESSORIES:

Accessories (E2599) for E2500 - E2510 are covered if the basic coverage criteria (1-7) for the base device are met and the medical necessity for each accessory is clearly documented in the formal evaluation by the SLP.

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.

GA – Waiver of liability statement on file

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

KX - Requirements specified in the medical policy have been met

Coding Information

HCPCS CODES:

E2500 SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, LESS THAN OR EQUAL TO 8 MINUTES RECORDING TIME

E2502 SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 8 MINUTES BUT LESS THAN OR EQUAL TO 20 MINUTES RECORDING TIME

E2504 SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 20 MINUTES BUT LESS THAN OR EQUAL TO 40 MINUTES RECORDING TIME

E2506 SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 40 MINUTES RECORDING TIME

E2508 SPEECH GENERATING DEVICE, SYNTHESIZED SPEECH, REQUIRING MESSAGE FORMULATION BY SPELLING AND ACCESS BY PHYSICAL CONTACT WITH THE DEVICE

E2510 SPEECH GENERATING DEVICE, SYNTHESIZED SPEECH, PERMITTING MULTIPLE METHODS OF MESSAGE FORMULATION AND MULTIPLE METHODS OF DEVICE ACCESS

E2511 SPEECH GENERATING SOFTWARE PROGRAM, FOR PERSONAL COMPUTER OR PERSONAL DIGITAL ASSISTANT

E2512 ACCESSORY FOR SPEECH GENERATING DEVICE, MOUNTING SYSTEM

E2599 ACCESSORY FOR SPEECH GENERATING DEVICE, NOT OTHERWISE CLASSIFIED

ICD-9 Codes that Support Medical Necessity

Not specified.

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." 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 upon request.

An order for all items must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS

General Information

code.

When codes E2511 - E2599 are billed, the claim must include the manufacturer name and the product name/number. If multicomponent mounting system, list each manufacturer and product name and number.

KX, GA, AND GZ MODIFIERS:

Suppliers must add a KX modifier to codes E2500 - E2599, and only if all of the coverage criteria in the "Indications and Limitations of Coverage and or Medical Necessity" section of this policy have been met.

If all of the criteria in the Indications and Limitations of Coverage and/or Medical Necessity section have not been met, the GA or GZ modifier must be added to the code. When there is an expectation of a medical necessity denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

Claims lines billed for E2500 – E2599 without a KX, GA, or GZ modifier will be rejected as missing information.

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

Advisory Committee Meeting Notes

Start Date of Comment Period

10/24/2000

End Date of Comment Period

12/19/2000

Start Date of Notice Period

04/01/2001

General Information

Revision History Number

SGD006

Revision History Explanation

Revision Effective Date: 12/01/2009

HCPCS CODES AND MODIFIERS:

Added: GA and GZ modifiers.

Revised: KX modifier.

DOCUMENTATION REQUIREMENTS:

Added: Multicomponent instructions.

Added: Instructions for the use of GA and GZ modifiers.

03/01/2008 - In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) LCD L11534 from DME PSC TriCenturion (77011) LCD L11534.

Revision Effective Date: 07/01/2007

INDICATIONS AND LIMITATIONS OF COVERAGE:

Removed: DMERC reference.

DOCUMENTATION REQUIREMENTS:

Removed: DMERC references.

06/01/2007 - In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

Revision Effective Date: 07/01/2005

LMRP converted to LCD and Policy.

DOCUMENTATION REQUIREMENTS:

Removed: Documentation requirements for E2511-E2599

Revision Effective Date: 04/01/2004

HCPCS CODES AND MODIFIERS:

Added: E2500, E2502, E2504, E2506, E2508, E2510, E2511, E2512, E2599

Deleted: K0615, K0616, K0617, K0541, K0543 – K0547

Revision Effective Date: 07/01/2003

HCPCS CODES AND MODIFIERS:

Deleted: K0542

Added: K0615, K0616, K0617

Revision Effective Date: 04/01/2003

HCPCS CODES AND MODIFIERS:

Added: EY modifier.

INDICATIONS AND LIMITATIONS OF COVERAGE:

Moved: Definitions to ILCMN section.

Added: Standard language concerning coverage of items without an order.

DOCUMENTATION REQUIREMENTS:

Added: Standard language concerning use of the EY modifier for items without an order.

The revision date listed below is the date the revision was published and not necessarily the effective date for the revision.

General Information

07/01/2002 – Replaced the ZX modifier with KX modifier. Corrected code K0546 to K0547 for mounting hardware in the Coding Guidelines section.

Reason for Change

Last Reviewed On Date

Related Documents

Article(s)

[A33770 - Speech Generating Devices \(SGD\) - Policy Article - December 2009](#)

LCD Attachments

There are no attachments for this LCD

Article for Speech Generating Devices (SGD) - Policy Article - December 2009 (A33770)

Contractor Information

Contractor Name

[NHIC, Corp.](#)

Contractor Number

16003

Contractor Type

DME MAC

Article Information

Article ID Number

A33770

Article Type

Article

Key Article

Yes

Article Title

Speech Generating Devices (SGD) - Policy Article - December 2009

Primary Geographic Jurisdiction

Connecticut
District of Columbia
Delaware
Massachusetts
Maryland
Maine
New Hampshire
New Jersey
New York - Entire State
Pennsylvania
Rhode Island
Vermont

DME Region Article Covers

Jurisdiction A

Original Article Effective Date

07/01/2005

Article Information

Article Revision Effective Date

12/01/2009

Article Text

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

Laptop computers, desktop computers, personal digital assistants (PDAs) or other devices that are not dedicated Speech Generating Devices (SGDs) are noncovered because they do not meet the definition of durable medical equipment (DME).

Software (E2511) that enables a laptop computer, desktop computer or PDA to function as an SGD is covered as an SGD; however, installation of the program or technical support are not separately reimbursable.

Upgrades to speech generating devices and/or software programs that are provided within the 5 year useful lifetime of the device will be denied as statutorily noncovered.

CODING GUIDELINES

Digitized speech (E2500, E2502 - E2506), sometimes referred to as devices with "whole message" speech output, utilize words or phrases that have been recorded by an individual other than the SGD user for playback upon command of the SGD user.

Synthesized speech (E2508, E2510), unlike the pre-recorded messages of digitized speech, is a technology that translates a user's input into device-generated speech. Users of synthesized speech SGDs are not limited to pre-recorded messages but rather can independently create messages as their communication needs dictate.

E2508 devices require that the user make physical contact with a keyboard, touch screen or other display containing letters.

E2510 devices permit the user multiple methods of message formulation and multiple methods of device access. Multiple methods of message formulation must include the capability for message selection by two or more of the following methods: letters, words, pictures or symbols. Multiple methods of access must include the capability to access the device by two or more of the following: direct physical contact with a keyboard or touch screen, indirect selection techniques with a specialized access device such as a joystick, head mouse, optical head pointer, switch, light pointer, infrared pointer, scanning device, or Morse Code.

Devices that have the capability to generate both digitized and synthesized speech are coded as E2508 or E2510, depending on the method of synthesized speech formulation and device access.

Codes E2500, E2502-E2506, E2508 and E2510 include all applicable software programs (whether they are on the device when shipped by the manufacturer or added by the supplier prior to delivery), batteries, battery chargers and AC adapters. These items may not be billed separately. There is also no separate payment if a nonintegrated keyboard is provided with an SGD.

Code E2511 is used to code for a speech generating software program that enables a laptop computer, desktop computer or PDA to function as an SGD. (Within this policy, the term SGD also describes these speech generating software programs.) The allowance for code E2511 includes the speech generating software program only. Installation of the program or technical support must not be billed separately. Code E2511 must not be used to code for software programs that are installed at the time of delivery of an SGD that is billed with codes E2500, E2502-E2506, E2508 or E2510. Code E2511 must not be used to code for software programs installed at the time of the initial provision of an SGD access device (E2599). E2511 is used for upgrade programs for a computer or PDA that are provided after the initial provision of the software.

Article Information

Mounting systems (E2512) are accessories that are needed to place the SGD, switches or other access devices within the reach of the patient. For systems with multiple components, bill system on a single claim line with one (1) unit of service.

Code E2599 is used for other separately payable accessories for speech generating devices. Examples include:

- An access device that enables the selection of letters, words or symbols via direct or indirect selection techniques. Access devices include, but are not limited to, optical head pointers, joysticks, switches and scanning devices. However, there is no separate billing for any software, interfaces, cables, adapters, interconnects or switches necessary for the access device to interface with the SGD. Those components should be included in the charge for the access device itself.
- Replacement accessories such as batteries, battery chargers and AC adapters.
- Upgrade software programs for E2500, E2502-E2506, E2508 or E2510 devices that are provided after the initial provision of the SGD.
- Electronic components that allow the SGD to be operated by the drive control interface of a power wheelchair.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

Coding Information

No Coding Information has been entered in this section of the article.

Other Information

Revision History Explanation

Revision Effective Date: 12/01/2009

CODING GUIDELINES:

Revised: Instructions for mounting systems (E2512)

Changed: SADMERC to PDAC.

03/01/2008 - In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC NHIC (16003) Article A33770 from DME PSC TriCenturion (77011) Article A33770.

Revision Effective Date: 07/01/2007

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added: Statement concerning non-coverage of replacements or upgrades during reasonable useful lifetime.

CODING GUIDELINES:

Revised definitions of E2511 and E2599.

06/01/2007 - In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this article was transitioned to DME PSC TriCenturion (77011) from DMERC Tricenturion (77011).

Other Information

Revision Effective Date: 07/01/2005

LMRP converted to LCD and Policy Article.

CODING GUIDELINES:

Deleted: E1900

Related Documents

LCD(s)

[L11534 - Speech Generating Devices](#)