Local Coverage Determination (LCD) for Speech Generating Devices (L11524)

**Contractor Information**

- **Contractor Name**: CGS Administrators, LLC
- **Contractor Number**: 18003
- **Contractor Type**: DME MAC
- **Jurisdiction**: J - G

**LCD Information**

- **LCD ID Number**: L11524
- **LCD Title**: Speech Generating Devices
- **Contractor's Determination Number**: SGD
- **Primary Geographic Jurisdiction**
  - Alabama
  - Arkansas
  - Colorado
  - Florida
  - Georgia
  - Louisiana
  - Mississippi
  - North Carolina
  - New Mexico
  - Oklahoma
  - Puerto Rico
  - South Carolina
  - Tennessee
  - Texas
  - Virginia
  - Virgin Islands
  - West Virginia
- **Oversight Region**: Region IV
- **DME Region LCD Covers**: Jurisdiction C
- **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 08/05/2011
- **Revision Ending Date**: 

**CMS National Coverage Policy**

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

**Indications and Limitations of Coverage and/or Medical Necessity**

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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 local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act § 1862(a)(1)(A) provisions, 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 reasonable and 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;
   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 reasonable and necessary.

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

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

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
GA – Waiver of liability statement issued as required by payer policy, individual case
GZ – Item or service expected to be denied as not reasonable and necessary
KX - Requirements specified in the medical policy have been met

HCPCS CODES:

SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, LESS THAN OR EQUAL TO 8 MINUTES RECORDING TIME
SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 8 MINUTES BUT LESS THAN OR EQUAL TO 20 MINUTES RECORDING TIME
SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 20 MINUTES BUT LESS THAN OR EQUAL TO 40 MINUTES RECORDING TIME
SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 40 MINUTES RECORDING TIME
SPEECH GENERATING DEVICE, SYNTHESIZED SPEECH, REQUIRING MESSAGE FORMULATION BY SPELLING AND ACCESS BY PHYSICAL CONTACT WITH THE DEVICE
SPEECH GENERATING DEVICE, SYNTHESIZED SPEECH, PERMITTING MULTIPLE METHODS OF MESSAGE FORMULATION AND MULTIPLE METHODS OF DEVICE ACCESS
SPEECH GENERATING SOFTWARE PROGRAM, FOR PERSONAL COMPUTER OR PERSONAL DIGITAL ASSISTANT
ACCESSORY FOR SPEECH GENERATING DEVICE, MOUNTING SYSTEM
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

Documentations 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 each item billed 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 code.

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

KX, GA, AND GZ MODIFIERS:

Suppliers must add a KX modifier to codes E2500 – E2599 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 denial as not reasonable and necessary, 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

Revision History Number 008

Revision History Explanation Revision Effective Date: 01/01/2011
INDICATIONS AND LIMITATIONS OF COVERAGE:
Revised: Preamble language
HCPCS CODES AND MODIFIERS:
Revised: GA modifier

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 CIGNA Government Services (18003) LCD L11517 from DME PSC TrustSolutions (77012) LCD L11517.

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 TrustSolutions (77012) from DMERC Palmetto GBA (00885).

Revision Effective Date: 07/01/2005
LMRP converted to LCD and Policy Article
DOCUMENTATION REQUIREMENTS:
Documentation requirements removed for E2511-E2599

Revision Effective Date: 04/01/2004
HCPCS CODES AND MODIFIERS:
Deleted: K0615, K0616, K0617, K0541, K0543 – K0547
Added: E2500, E2508 – E2512, E2599

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
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.

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

07/01/2001 – Replaced the ZX modifier with KX modifier. Corrected code K0546 to K0547 for mounting hardware in the Coding Guidelines section.
08/05/2011 - The Jurisdiction C contractor adopted a new business name. This LCD revision only includes the change from CIGNA Government Services to CGS Administrators, LLC. No coverage information was included in this revision and no provider action is needed regarding this revision.

Reason for Change Maintenance (annual review with new changes, formatting, etc.)

Related Documents
Article(s)
A33754 - Speech Generating Devices (SGD) - Policy Article - Effective January 2011 opens in new window

LCD Attachments
There are no attachments for this LCD.

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All Versions
Updated on 03/08/2012 with effective dates 08/05/2011 - N/A
Updated on 08/04/2011 with effective dates 08/05/2011 - N/A
Updated on 02/25/2011 with effective dates 01/01/2011 - 08/04/2011
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