

**LCD ID Number**

L108

**LCD Title**

Speech Generating Devices

**Contractor's Determination Number**

SGD

**CMS National Coverage Policy**

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

**DME Region LCD Covers**

Jurisdiction D

**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.

A speech generating device (E2500, E2508 - E2511, E2502 - E2506) 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 medically necessary.

Codes E2500, E2508 - E2511, and E2502 - E2506 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, E2508, E2510, and E2502 - E2506 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.

### **Coverage Topic**

Durable Medical Equipment

## 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.**

#### 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" (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 treating 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.

Suppliers must add a KX modifier to codes E2500, E2508 - E2599, and E2502 - E2506 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 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.

When codes E2511 - E2599 are billed, the claim must include a narrative description of the item, the manufacturer, and the product name/number.

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

**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**

SGD005

**Revision History Explanation**

Revision Effective Date: 07/01/2005  
LMRP converted to LCD and Policy  
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.

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC Electronic Data Systems Corp. (77006) from DMERC CIGNA Government Services (05655).

**Last Reviewed On Date**

**Related Documents****Article(s)**

[A33679 - Speech Generating Devices - Policy Article - Effective July 2005](#)

**LCD Attachments**

There are no attachments for this LCD.