

# Local Coverage Determination (LCD): Speech Generating Devices (SGD) (L33739)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
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

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska 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**

L33739

**Original Effective Date**

For services performed on or after 10/01/2015

**LCD Title**

Speech Generating Devices (SGD)

**Revision Effective Date**

For services performed on or after 01/01/2020

**Proposed LCD in Comment Period**

N/A

**Revision Ending Date**

N/A

**Source Proposed LCD**

N/A

**Retirement Date**

N/A

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**Notice Period Start Date**

N/A

**Notice Period End Date**

N/A

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## **CMS National Coverage Policy**

CMS Pub. 100-03, (Medicare National Coverage Determinations Manual), Chapter 1, Section 50.1

### **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.

For the purposes of this policy, speech generation is defined as audible generation of words or phrases and in addition, may include:

1. Communication via written text (i.e., email or text (SMS) messaging); or,
2. Communication via phone messaging.

Speech generating devices are defined as durable medical equipment that provides an individual who has a severe speech impairment with the ability to meet his or her functional, speaking needs. Speech generating devices are speech aids consisting of devices or software that generate speech (as defined above) and are used solely by the individual who has a severe speech impairment. The speech is generated using one of the following methods:

- Digitized audible/verbal speech output, using prerecorded messages;
- Synthesized audible/verbal speech output which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
- Synthesized audible/verbal speech output which permits multiple methods of message formulation and multiple methods of device access; or
- Software that allows a computer or other electronic device to generate speech.

A speech generating device (SGD) (E2500, E2502, E2504, E2506, E2508, E2510, E2511) is covered when all of the following criteria (1-7) are met:

1. Prior to the delivery of the SGD, the beneficiary 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 beneficiary 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 beneficiary of the upgrade compared to the initially provided SGD; and

2. The beneficiary's medical condition is one resulting in a severe expressive speech impairment; and
3. The beneficiary'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 beneficiary'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 beneficiary's treating practitioner prior to ordering the device; and
7. The SLP performing the beneficiary 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, E2502, E2504, E2506, E2508, E2510, E2511 perform the same essential function - speech generation. Therefore, claims for more than one SGD will be denied as not reasonable and necessary.

The capability to download updates to the covered features of the device from the manufacturer or supplier of the device is covered. See related Policy Article for additional Non-Medical Necessity Coverage and Payment Rules.

#### **ACCESSORIES:**

Claims for accessories to SGDs must meet the general coverage requirements for the base SGD described in criteria 1-7 above. Claims for SGD accessories for beneficiaries who do not meet criteria 1-7 above will be denied as not reasonable and necessary.

Alternative input devices are covered when a beneficiary is unable to use standard input devices. Claims for alternative input devices for beneficiaries who are able to use standard input devices will be denied as not reasonable and necessary.

Eye tracking and gaze interaction accessories for speech generating devices are covered when furnished to individuals with a demonstrated medical need for such accessories.

If the SGD is denied as not reasonable and necessary, any related accessories will be denied as not reasonable and necessary.

#### **GENERAL**

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

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 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

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## **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

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:**

**Group 1 Codes:**

CODE	DESCRIPTION
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

## 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

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## **Revision History Information**



REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
01/01/2020	R6	<p>Revision Effective Date: 01/01/2020            COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:            Revised: Format of HCPCS code references, from code spans to individually-listed HCPCS            Revised: "physician" to "practitioner"            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"            DOCUMENTATION REQUIREMENTS:            Revised: "physician's" to "treating practitioner's"            GENERAL DOCUMENTATION REQUIREMENTS:            Revised: Prescriptions (orders) to SWO</p> <p><i>02/27/2020: 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, HCPCS code changes, and non-substantive corrections (listing individual HCPCS codes instead of a HCPCS code-span).</i></p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> <li>• Other</li> </ul>
01/01/2017	R5	<p>No changes have been made to this LCD.</p> <p><i>04/05/2018: 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.</i></p>	<ul style="list-style-type: none"> <li>• Other</li> </ul>
01/01/2017	R4	<p>Revision Effective Date: 01/01/2017            COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:            Removed: Standard Documentation Language            Added: New reference language and directions to Standard Documentation Requirements            Added: General Requirements            DOCUMENTATION REQUIREMENTS:</p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>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</p>	
07/01/2016	R3	<p>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.</p>	<ul style="list-style-type: none"> <li>• Change in Assigned States or Affiliated Contract Numbers</li> </ul>
10/01/2015	R2	<p>Revision Effective Date: 07/29/2015 (October 2015 Publication)  COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:  Added: SGD definitional language from NCD 50.1  Added: Capability to download updates  Added: Gleason Act language for eye gaze accessories  POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:  Added: Documentation requirement for SGD and accessories</p>	<ul style="list-style-type: none"> <li>• NCD Supplementation</li> </ul>
10/01/2015	R1	<p>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  Added: Instructions for Equipment Retained from a Prior Payer  Revised: Repair to beneficiary-owned DMEPOS</p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> </ul>

# Associated Documents

## Attachments

N/A

## Related Local Coverage Documents

Article(s)

A52469 - Speech Generating Devices (SGD) - Policy Article

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

## Related National Coverage Documents

N/A

## Public Version(s)

Updated on 02/21/2020 with effective dates 01/01/2020 - N/A

Updated on 04/27/2017 with effective dates 01/01/2017 - 12/31/2019

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

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# Keywords

N/A

**END OF LOCAL COVERAGE DETERMINATION**

Per the Code of Federal Regulations, 42 C.F.R § 426. 325, only those portions of the currently effective Local Coverage Determination (LCD) that are based on section 1862(a)(1)(A) of the Social Security Act, may be challenged through an acceptable complaint as described in 42 C.F.R § 426.400. Also, per 42 C.F.R § 426.325 items that are not reviewable, and therefore cannot be challenged, include the Policy Article. Please note the distinction of the documents when reviewing the materials.

# Local Coverage Article: Speech Generating Devices (SGD) - Policy Article (A52469)

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## Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
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

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska 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

## Article Information

### General Information

**Article ID**

A52469

**Original Effective Date**

10/01/2015

**Original ICD-9 Article ID**

[A33754](#)

[A47099](#)

[A33770](#)

[A33679](#)

**Revision Effective Date**

01/01/2020

**Revision Ending Date**

N/A

**Article Title**

Speech Generating Devices (SGD) - Policy Article

**Retirement Date**

N/A

**Article Type**

Article

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## **Article Guidance**

### **Article Text:**

### **NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES**

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. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Speech generating devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement, the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

As noted in the related Local Coverage Determination (LCD), speech generation defined as audible generation of words or phrases and in addition, may include:

1. Communication via written text (i.e., email or text (SMS) messaging); or,
2. Communication via phone messaging.

To meet the DME benefit category requirements, the speech generating device must meet all of the following requirements:

1. Can withstand repeated use; and,
2. Has an expected life of at least 3 years; and,
3. Is primarily and customarily used to serve a medical purpose; and,
4. Generally is not useful to an individual in the absence of an illness or injury; and,
5. Is appropriate for use in the home; and,
6. Be limited to use by a patient with a severe speech impairment; and,
7. Be primarily used for the purpose of generating speech, as defined above.

For criterion 7, a device utilizing tablet, smartphone or computer hardware must be designed by the manufacturer to function solely as a speech generation device, as defined above, at the time of initial issue.

Desktop, laptop, tablet, smartphone and other hand-held computers (i.e. general computing devices) are not considered DME because they do not meet criteria 3, 4, 6 and 7 above, even though they may serve a medical purpose. Medicare will reimburse for speech generating software only (HCPCS code E2511) when installed on a general computing device. The device itself must be coded A9270.

The following features of a speech generating device are non-covered because they do not fall within the scope of the durable medical equipment benefit:

1. Specific features of a speech generating device that are not used by the individual who has a severe speech impairment to meet his or her functional speaking needs.
2. Video communications or conferencing.
3. Any computing hardware or software not necessary to allow for generation of speech, email, text or phone messages. Examples include, but are not limited to:
  1. Hardware or software used to create documents and spreadsheets; or,
  2. Hardware or software used to play games or music.

Internet service provider (ISP), phone service subscriptions or any modification to a patient's home to allow use of the speech generating device are non-covered because such services or modifications could be used for non-medical equipment such as standard phones or general computing devices.



A carrying case (including shoulder strap or carrying handle, any type) (E2599) is a convenience item and is denied as non-covered.

Accessories used with non-covered devices will be denied as non-covered.

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 non-covered.

## **REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217)**

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provides a list of the specified codes, which is periodically updated. The link will be located here once it is available.

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD- related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD prior to delivery, it will be eligible for coverage.

## **POLICY SPECIFIC DOCUMENTATION REQUIREMENTS**

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

The medical necessity requirements for each accessory (E2599) for E2500, E2502, E2504, E2506, E2508, E2510 must be clearly documented in the formal evaluation by the SLP. For alternative input devices, there must be information in the SLP evaluation about why standard input access devices are unable to be used.

When codes E2511, E2512, E2599 are billed, the claim must include all of the following information:

- Description of the item or service
- Manufacturer name
- Product name and number

If billing a multicomponent mounting system, list each component's manufacturer and product name and number.

## **MODIFIERS**

## KX, GA, AND GZ MODIFIERS:

Suppliers must add a KX modifier to codes E2500, E2502, E2504, E2506, E2508, E2510, E2511, E2512, E2599 only if all of the coverage criteria in the "Coverage Indications, Limitations and/or Medical Necessity" section of the related LCD have been met and evidence of such is retained in the supplier's files and available upon request.

If all of the criteria in the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD 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, E2502, E2504, E2506, E2508, E2510, E2511, E2512, E2599 without a KX, GA, or GZ modifier will be rejected as missing information.

## **CODING GUIDELINES**

Code A4601 describes any lithium ion rechargeable battery used with an SGD or related accessory.

Digitized speech (E2500, E2502, E2504, 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, E2504, E2506, E2508 and E2510 include all applicable speech generating 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.

To be coded as E2510, a desktop, tablet, smartphone or modified laptop computer must only be capable of speech generation, as defined above. General computing devices (i.e., desktop, laptop, tablet, smartphone or other hand-held computers) with additional non-covered features (see Non-Medical Necessity Coverage and Payment Rules above) included at the time of initial issue must be coded A9270.

A device that provides the same functionality as a desktop, tablet, smartphone or laptop computer at the time of issuance is considered a general use computer and is not considered a speech generating device.

Effective for claims with dates of service on or after June 1, 2016, the only products which may be billed to Medicare using code E2510 are those for which a written coding verification has been made by the PDAC contractor and are listed on the Product Classification List in the Durable Medical Equipment Coding System (DMECS) maintained on the PDAC website. Products which have not received coding verification review from the PDAC must be billed with code A9270.

Code E2511 is used to code for speech generating software programs that enable a laptop computer, desktop computer, tablet, smartphone or other hand-held general computing device to generate speech. 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 (codes E2500, E2502, E2504, 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 accessory or alternative access device. Software for the accessory or alternative access device is included in the reimbursement for the accessory or alternative access device. Claims for code E2511 billed with an accessory or alternative access device will be denied as unbundling.

E2511 is used for upgrade programs for SGDs (codes E2500, E2502, E2504, E2506, E2508 or E2510) or when code E2511 is used to bill for software only when installed on a general computing device. Replacement or upgrade of speech generating software loaded onto a covered speech generating device is not covered unless the replacement software is necessary due to a change in the patient's condition, or in cases where the software has been lost, stolen, irreparably damaged, or has been in continuous use for the reasonable useful lifetime of 5 years.

Mounting systems and stands (E2512) are accessories that are needed to place the SGD, switches or other access devices within the reach of the beneficiary. For systems with multiple components, bill system on a single claim line with one (1) unit of service. 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 are included in the reimbursement for the access device itself.

A protective case or cover, any type (E2599) is not separately payable as they are required to make the SGD durable under the definition of DME (see criterion 2 above under Non-Medical Necessity Coverage and Payment Rules). Claims for protective cases or covers when billed with a covered SGD will be denied as unbundled.

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

- Ocular tracking device, any type, describes an SGD accessory used with an SGD or SGD software to allow a speech-impaired person to use his or her eyes to communicate. Ocular tracking devices track the user's eye movement and determine where on screen their gaze is targeted.
- Head control mouse, any type, describes an SGD accessory that monitors head movement and translates those movements into actions by the pointer on the SGD screen.
- Alternative input device, any type, describes any accessory other than an ocular tracking device or head control mouse, not integrated into the SGD hardware, used to control the actions of an SGD. Examples of alternative input devices include (not all-inclusive): specialty keyboards, joysticks, trackballs, trackpads, buddy buttons, jelly beans, beamers, roller balls, round pads, pal pads.
- Protective key guard, any type describes an overlay for a keyboard, alternative input device or SGD screen that assists the beneficiary in preventing inadvertent selection of a button, icon or other input.
- Protective case or cover, any type describes any protective case or cover used to enclose the SGD to prevent the ingress of liquids, dirt, dust, etc. (see above Coding Guidelines for more information).

- Carrying case, includes shoulder strap or carrying handle, any type describes any soft-sided or hard-sided carrying container for the SGD and any related accessories (See Non-Medical Necessity Coverage and Payment Rules for more information).
- 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.

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## Coding Information

### CPT/HCPCS Codes

N/A

### ICD-10 Codes that Support Medical Necessity

N/A

### ICD-10 Codes that DO NOT Support Medical Necessity

N/A

### Additional ICD-10 Information

N/A

### 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.

N/A

### 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.

## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2020	R8	<p>Revision Effective Date: 01/01/2020</p> <p>NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:            Removed: REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO 42 CFR 410.38(g) section            REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217):            Added: Section and related information based on Final Rule 1713</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:            Revised: Format of HCPCS code references, from code spans to individually-listed HCPCS</p> <p>MODIFIERS:            Revised: Format of HCPCS code references, from code spans to individually-listed HCPCS</p> <p>CODING GUIDELINES:            Revised: Format of HCPCS code references, from code spans to individually-listed HCPCS</p> <p>ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY:            Revised: Section header "ICD-10 Codes that are Covered" updated to "ICD-10 Codes that Support Medical Necessity"</p> <p>ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY:            Revised: Section header "ICD-10 Codes that are Not Covered" updated to "ICD-10 Codes that DO NOT Support Medical Necessity"</p> <p><i>02/27/2020: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2017	R7	<p><i>02/14/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This is an article and not a local coverage determination.</i></p>
01/01/2017	R6	<p>Revision Effective Date: 01/01/2017</p> <p>CODING GUIDELINES:            Added: Coding Verification Review for E2510</p> <p><i>04/05/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2017	R5	Revision Effective Date: 01/01/2017 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Removed: Standard Documentation Language Added: 42 CFR 410.38(g) POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Documentation and billing instructions for E2511-E2599 (previously in the LCD) and Modifier instructions RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements Language Article
07/01/2016	R4	Effective July 1, 2016 oversight for DME MAC Articles 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 Articles.
10/01/2015	R3	10/16/2015 - Changed title to remove effective date
10/01/2015	R2	Revision Effective Date: 07/29/2015 (October 2015 Publication) NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Added: SGD definitional language from NCD 50.1 Added: Non-coverage statements from NCD 50.1 CODING GUIDELINES: Added: Description of HCPCS Code A4601 Added: Definitions of SGD accessories and examples
10/01/2015	R1	Revision Effective Date: 10/31/2014 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Removed: "When required by state law" from ACA new prescription requirements  Revised: Face-to-Face Requirements for treating practitioner

## Associated Documents

### Related Local Coverage Document(s)

Article(s)

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

LCD(s)

L33739 - Speech Generating Devices (SGD)

### Related National Coverage Document(s)

N/A

### Statutory Requirements URL(s)

N/A

### Rules and Regulations URL(s)

N/A

**CMS Manual Explanations URL(s)**

N/A

**Other URL(s)**

N/A

**Public Version(s)**

Updated on 02/21/2020 with effective dates 01/01/2020 - N/A

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Updated on 04/27/2017 with effective dates 01/01/2017 - N/A

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# Keywords

N/A