

Article - Speech Generating Devices (SGD) - Policy Article (A52469)

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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, LLC	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

Article Information

General Information

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Article Title

Speech Generating Devices (SGD) - Policy Article

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 (PCL) in the Durable Medical Equipment Coding System (DMECS) maintained on the PDAC website.

If a product is billed to Medicare using a HCPCS code that requires written coding verification review, but the product is not on the PCL for that particular HCPCS code, then the claim line will be denied as incorrect coding.

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.

Coding Information

CPT/HCPCS Codes N/A
ICD-10-CM Codes that Support Medical Necessity N/A

ICD-10-CM 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 article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article 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 article, 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 article should be assumed to apply equally to all Revenue Codes.

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2020	R9	<p>Revision Effective Date: 01/01/2020</p> <p>CODING GUIDELINES:</p> <p>Added: "(PCL)" after reference to "Product Classification List"</p> <p>Revised: Coding verification review information, to include incorrect coding denial language for products billed using HCPCS that require written coding verification review</p> <p><i>03/11/2021: 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>
01/01/2020	R8	<p>Revision Effective Date: 01/01/2020</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		<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 POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Revised: Format of HCPCS code references, from code spans to individually-listed HCPCS MODIFIERS: Revised: Format of HCPCS code references, from code spans to individually-listed HCPCS CODING GUIDELINES: Revised: Format of HCPCS code references, from code spans to individually-listed HCPCS 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" 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 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>
01/01/2017	R5	<p>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</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		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 Documents

Articles

[A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs](#)

LCDs

[L33739 - Speech Generating Devices \(SGD\)](#)

Related National Coverage Documents

N/A

Statutory Requirements URLs

N/A

Rules and Regulations URLs

N/A

CMS Manual Explanations URLs

N/A

Other URLs

N/A

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