

# Speech Generating Devices

## Tricenturion

Contractor Information	
Contractor Name	Tricenturion
Contractor Number	77011
Contractor Type	DMERC
LMRP Information	
LMRP Database ID Number	L11534
LMRP Version Number	4
LMRP Title	Speech Generating Devices
Contractor's Policy Number	SGD20030401
AMA CPT Copyright Statement	CPT codes, descriptions and other data only are copyright 2002 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply.
CMS National Coverage Policy	Coverage Issues Manual 60-9, 60-23
Primary Geographic Jurisdiction	CT DE MA ME NH NJ NY PA RI VT
Oversight Region	Region III
CMS Consortium	Northeast
DMERC Region LMRP Covers	Region A
Original Policy Effective Date	For services performed on or after 07/01/2001
Original Policy Ending Date	
Revision Effective Date	For services performed on or after 04/01/2003
Revision Ending Date	
LMRP Description	Speech generating devices.
Indications and Limitations of Coverage and/or Medical Necessity	<p><b>COVERAGE AND PAYMENT RULES:</b></p> <p>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</p>

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 (K0541 - K0545) 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 K0541 - K0544 and code K0545 perform the same essential function - speech generation. Therefore, claims for more than one SGD will be denied as not medically necessary.

	<p>Laptop computers, desktop computers, PDAs or other devices that are not dedicated SGDs are noncovered because they do not meet the definition of durable medical equipment (DME).</p> <p>Software (K0545) 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.</p> <p>ACCESSORIES:</p> <p>Accessories (K0547) for K0541 - K0544 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.</p>
<b>CPT/HCPCS Section</b>	Durable Medical Equipment Regional DMERCs
<b>Benefit Category</b>	Durable Medical Equipment
<b>Coverage Topic</b>	Durable Medical Equipment
<b>Coding Information</b>	
<b>CPT/HCPCS Codes</b>	<p>The appearance of a code in this section does not necessarily indicate coverage.</p> <p>HCPCS MODIFIERS:</p> <p>EY - No physician or other health care provider order for this item or service. KX - Specific required documentation on file.</p> <p>HCPCS CODES:</p> <p>K0541 SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, LESS THAN OR EQUAL TO 8 MINUTES RECORDING TIME</p> <p>K0542 SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 8 MINUTES RECORDING TIME</p> <p>K0543 SPEECH GENERATING DEVICE, SYNTHESIZED SPEECH, REQUIRING MESSAGE FORMULATION BY SPELLING AND ACCESS BY PHYSICAL CONTACT WITH THE DEVICE</p> <p>K0544 SPEECH GENERATING DEVICE, SYNTHESIZED SPEECH, PERMITTING MULTIPLE METHODS OF MESSAGE FORMULATION AND MULTIPLE METHODS OF DEVICE ACCESS</p> <p>K0545 SPEECH GENERATING SOFTWARE PROGRAM, FOR PERSONAL COMPUTER OR PERSONAL DIGITAL ASSISTANT</p> <p>K0546 ACCESSORY FOR SPEECH GENERATING DEVICE, MOUNTING SYSTEM</p> <p>K0547 ACCESSORY FOR SPEECH GENERATING DEVICE, NOT OTHERWISE CLASSIFIED</p>
<b>Not Otherwise Classified (NOC)</b>	

<b>ICD-9 Codes that Support Medical Necessity</b>	Not specified.
<b>Diagnoses that Support Medical Necessity</b>	Not specified.
<b>ICD-9 Codes that DO NOT Support Medical Necessity</b>	Not specified.
<b>Non-Medical Necessity ICD-9 Codes Asterisk Explanation</b>	
<b>Diagnoses that DO NOT Support Medical Necessity</b>	Not specified.
<b>Reasons for Denials</b>	Items listed in this policy will be denied as not medically necessary when provided for conditions other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section unless it specifically states in that section that they will be denied as noncovered.
<b>Non-covered ICD-9 Codes</b>	
<b>Non-covered Diagnoses</b>	Not specified.
<b>Coding Guidelines</b>	<p>Digitized speech (K0541, K0542), 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.</p> <p>Synthesized speech (K0543, K0544), 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.</p> <p>K0543 devices require that the user make physical contact with a keyboard, touch screen or other display containing letters.</p> <p>K0544 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.</p> <p>Speech generating software programs (K0545) enable a laptop computer, desktop computer or personal digital assistant (PDA) to function as an SGD. Within this policy, the term SGD also describes these speech generating software programs.</p> <p>Personal digital assistants (PDAs) are handheld devices that integrate the functions of a small computer with features such as a cell phone, personal organizer, electronic mail or pager. Information may be input via a pen-based system using a stylus and handwriting recognition software, keyboard or downloaded from a personal computer using special cables and software.</p>

Mounting systems (K0546) are devices necessary to place the SGD device, switches and other access devices within the reach of the patient.

Accessories for speech generating devices (K0547) include, but are not limited to, access devices that enable selection of letters, words or symbols via direct or indirect selection techniques. Examples of access devices include, but are not limited to, optical head pointers, joysticks, switches, wheelchair integration devices and SGD scanning devices. In addition, replacement accessories such as batteries, battery chargers and AC adapters are included in this code.

Code E1900 (Synthesized speech augmentative communication device with dynamic display), effective for dates of service on or after the effective date of this policy, is no longer valid for submission to the DMERC.

Codes K0541 and K0542 must be used to code devices that generate only digitized speech output. Codes K0543 and K0544 must be used to code devices that generate synthesized speech. Devices that have the capability to generate both digitized and synthesized speech must be coded K0543 or K0544, depending on the method of synthesized speech formulation and device access.

Codes K0541 - K0544 include the device, any applicable software, batteries, battery chargers, and AC adapters. These items may not be billed separately.

Code K0545 is used to code for a speech generating software program that enables a laptop computer, desktop computer or personal digital assistant (PDA) to function as an SGD. The allowance for code K0545 includes the speech generating software program only. Installation of the program or technical support must not be billed separately. Code K0545 must not be used to code software included with the initial provision of the SGD (K0541 - K0544) since the software cost is included in the reimbursement for those SGD codes. In addition, code K0545 must not be used to code software included with the initial provision of the access device (K0547) since the software cost is included in the reimbursement for the access device.

Upgrades to K0545 are subsequent versions of a speech generating software program that may include enhanced features or other improvements. Upgrades to K0545 must be coded K0545.

Mounting systems necessary to place the SGD device, switches and other access devices within the reach of the patient must be coded K0546.

Accessories to SGDs such as access devices should be coded K0547. There should be no separate billing of any software, interfaces, cables, adapters, interconnects, or switches necessary for the accessory to interface with the SGD (K0541 - K0545).

Upgrades to K0541 - K0544 are subsequent versions of the device's software program or memory modules that may include enhanced features or other improvements. Upgrades to K0541 - K0544 must be coded K0547.

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these items.

<b>General Information</b>	
<b>Documentation Requirements</b>	<p>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. section 1395I(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.</p> <p>An order for all items 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.</p> <p>Suppliers must add a KX modifier to codes K0541 - K0547 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.</p> <p>When codes K0545 - K0547 are billed, the claim must include a narrative description of the item, the manufacturer, the model name or number (if applicable), and information justifying the medical necessity for the item. This information must be included with the claim if submitted hard copy or transcribed into the narrative field of an electronic claim.</p> <p>Refer to the Supplier Manual for more information on documentation requirements.</p>
<b>Appendices</b>	
<b>Footnotes</b>	
<b>Utilization Guidelines</b>	Refer to Indications and Limitations of Coverage and/or Medical Necessity.
<b>Other Comments</b>	<p>Speech generating devices (SGDs) are defined as speech aids that provide individuals with severe speech impairment the ability to meet their functional speaking needs.</p> <p>Speech-language pathologists (SLPs) are licensed health professionals educated at the graduate level in the study of human communication, its development and its disorders. The SLP must hold a Certificate of Clinical Competence (CCC) in speech-language pathology from the American Speech-Language-Hearing Association.</p>
<b>Sources of Information and Basis for Decision</b>	Reserved for future use.
<b>Advisory Committee Meeting Notes</b>	
<b>Start Date of Comment Period</b>	10/24/2000
<b>End Date of Comment Period</b>	12/19/2000
<b>Start Date of Notice Period</b>	04/01/2001

<b>Revision History Number</b>	SGD002
<b>Revision History Explanation</b>	<p>Revision Effective Date: 04/01/2003</p> <p>HCPCS CODES AND MODIFIERS: Added: EY</p> <p>INDICATIONS AND LIMITATIONS OF COVERAGE: Moved Definitions to ILCMN section. Added standard language concerning coverage of items without an order.</p> <p>DOCUMENTATION REQUIREMENTS: Added standard language concerning use of the EY modifier for items without an order.</p> <p>The revision date listed below is the date the revision was published and not necessarily the effective date for the revision.</p> <p>07/01/2002 – Replaced the ZX modifier with KX modifier. Corrected code K0546 to K0547 for mounting hardware in the Coding Guidelines section.</p>
<b>Disclaimer Specialty Name</b>	
<b>LMRP Attachments</b>	There are no attachments for this LMRP

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