Speech Generating Devices

Adopted from National Government Services website

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan 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. Please refer to individual product lines certificates of coverage for possible exclusions of benefit.

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. 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.

Suppliers are to follow The Health Plan requirements for precertification, as applicable.

Speech generating devices require precertification and physician face-to-face for HCPCS codes E2502, E2506, E2508, and E2510.

As of 12/1/14 HCPCS code E2510 requires PDAC verification.

<table>
<thead>
<tr>
<th>CMS National Coverage Policy</th>
<th>CMS Publication 100-3 Medicare National Coverage Determinations Manual, Chapter 1, Section 50.1, 280.1</th>
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<tbody>
<tr>
<td>DME Region LCD Covers</td>
<td>Jurisdiction B-C</td>
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</table>
| Review/Revision Effective Date| For service performed on or after 10/31/13
|                               | **Reviewed /Revised:** 07/01/17, 09/01/16, 10/01/15, 09/09/14                                    |
| The Health Plan               | Plans will follow Coverage Determination posted on the CGS website unless otherwise indicated in sections of this policy, contractual agreements, or benefit plan documents. |

**DESCRIPTION**

A speech generating device is an electronic device used to supplement speech for people with aphasia. They allow the user to select messages to be spoken aloud, meeting the majority of their communication needs. SGD technology ranges from simple to complex. They are also referred to as voice-output communication aids (VOCA).
**COVERAGE GUIDELINES**

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 member 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 member 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 member of the upgrade compared to the initially provided SGD;

And,

2. The member's medical condition is one resulting in a severe expressive speech impairment; and,
3. The member'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 member's speech impairment will benefit from the device ordered; and,
6. A copy of the SLP written evaluation and recommendation have been forwarded to the member's treating physician prior to ordering the device; and,
7. The SLP performing the member 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.

**NONCOVERAGE STATEMENT**

These include West Virginia Medicaid – see their noncoverage statement Chapter 530.7

Upgrades to, or subsequent versions of the speech generating device software program of memory modules that may include enhanced features or other improvements

1. Any device that is not a dedicated augmentative communication/speech generating device or can run software for purposes other than speech generating device (e.g., Word processing application, accounting program, or other non-medical functions)
2. Augmentative communication (AC)/speech generating systems or devices intended to meet social, educational, vocational or non-medical needs
3. Any device that allows input of information via a pen-based system using a stylus and handwriting recognition software, keyboard, or downloaded from a personal computer using special cables and software

4. Handheld devices, such as personal digital assistants, that integrate the functions of a small computer with features such as a cell phone, personal organizer, electronic mail, or pager are noncovered because they do not meet the definition of durable medical equipment (DME). They are not considered primarily medical in nature.

5. Multiple ACs or software programs that perform the same essential function are considered a duplication of services and are not medically 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.

6. Laptop computers or desktop computers which may be programmed to perform the same function as a speech generating device are noncovered because they do not meet the definition of durable medical equipment (DME). They are not considered primarily medical in nature.

7. Printers (which are not a built-in component of an augmentative communication/speech generating device), printer paper, printer cables

8. Environmental control devices which are not a built-in component

9. Purchase of a new personal computer, repair or replacement of a previously owned personal computer or any related hardware are noncovered because they do not meet the definition of durable medical equipment (DME). They are not considered primarily medical in nature.

10. Extended vocabulary software packages

11. An AC device provided without severe speech impairment.

Upgrades to speech generating devices and/or software programs that are provided within the five-year useful lifetime of the device will be denied as statutorily noncovered.

There should be no separate billing of any software, interfaces, cables, adapters, interconnects, and switches necessary for the accessory to interface with the SGD. (See Billing Guidelines)

Repairs to non-dedicated devices (laptops, smart phones, tablets) hosting an SGD are noncovered.

**CODING INFORMATION**

*CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.*

<table>
<thead>
<tr>
<th>HCPCS MODIFIERS</th>
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<tr>
<td>EY</td>
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<tr>
<td>GA</td>
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<td>GZ</td>
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<td>KX</td>
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**HCPCS CODES**
### SPEECH GENERATING DEVICES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>E2500</td>
<td>SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, LESS THAN OR EQUAL TO 8 MINUTES RECORDING TIME</td>
</tr>
<tr>
<td>E2502</td>
<td>SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 8 MINUTES BUT LESS THAN OR EQUAL TO 20 MINUTES RECORDING TIME</td>
</tr>
<tr>
<td>E2504</td>
<td>SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 20 MINUTES BUT LESS THAN OR EQUAL TO 40 MINUTES RECORDING TIME</td>
</tr>
<tr>
<td>E2506</td>
<td>SPEECH GENERATING DEVICE, DIGITIZED SPEECH, USING PRE-RECORDED MESSAGES, GREATER THAN 40 MINUTES RECORDING TIME</td>
</tr>
<tr>
<td>E2508</td>
<td>SPEECH GENERATING DEVICE, SYNTHESIZED SPEECH, REQUIRING MESSAGE FORMULATION BY SPELLING AND ACCESS BY PHYSICAL CONTACT WITH THE DEVICE</td>
</tr>
<tr>
<td>E2510</td>
<td>SPEECH GENERATING DEVICE, SYNTHESIZED SPEECH, PERMITTING MULTIPLE METHODS OF MESSAGE FORMULATION AND MULTIPLE METHODS OF DEVICE ACCESS</td>
</tr>
<tr>
<td>E2511</td>
<td>SPEECH GENERATING SOFTWARE PROGRAM, FOR PERSONAL COMPUTER OR PERSONAL DIGITAL ASSISTANT</td>
</tr>
<tr>
<td>E2512</td>
<td>ACCESSORY FOR SPEECH GENERATING DEVICE, MOUNTING SYSTEM</td>
</tr>
<tr>
<td>E2599</td>
<td>ACCESSORY FOR SPEECH GENERATING DEVICE, NOT OTHERWISE CLASSIFIED</td>
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There are no specific diagnoses or ICD-10 codes that indicate medical necessity.

### 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." For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes 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 with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
   a. Member’s name
   b. Date
   c. Description of item. The medical record must contain the information that supports the request for each item, and must be submitted with the precertification, if the item requires precertification, or with the claim, if no precertification was required
   d. Order must include diagnosis code
   e. Physician signature with date. Date stamps are not appropriate
f. Quantity of items required and duration – a new order is required if these is an increase in the quantity of the supply used per month and/or the type of supply used. The supplier is to contact The Health Plan in this instance to update referral.

2. There must be documentation in the supplier’s records to support the medical necessity of that item. This information but must be available upon request usually with precertification per The Health Plan policy.

3. Proof of delivery to be kept on file by the provider of the item.

Note: If templates or forms are submitted, (i.e., A Medicare Certificate of Medical Necessity, and/or a provider created form), The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, home health records.

Note: Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

Precertification is required when supplies used are greater than the usual maximum quantity listed in above. There must be adequate, clear documentation in the medical record corroborating the medical necessity of this amount. This documentation is to be submitted with precertification.

**SPEECH GENERATING DEVICE PROVIDED WHILE MEMBER IN PART A FACILITY COVERED STAY**

Reimbursement for a speech generating device provided to a member while the member is covered in a Part A facility (Hospital or inpatient acute rehabilitation or long-term acute care facility), will be included in the facility reimbursement if the device is intended for use while the member is in the facility for inpatient treatment or rehabilitation. A separate claim from a durable medical equipment provider must not be submitted in this situation.

Reimbursement for an electrical stimulator provided while a member is in a SNF receiving Part A services, will be reimbursed according to the individual facility’s contract and it must meet the above guidelines and be medically necessary for home use.

**NEW MEMBER’S WITH EXISTING SPEECH THERAPY DEVICE**

For those members who are new to The Health Plan but are in a current rental period through their previous insurance, The Health Plan requires a review of testing done, compliance download, and the face-to-face visit with physician that qualified the member for the device.

The Health Plan will reimburse the remainder of The Health Plan’s rental period up to the contracted purchase amount of the device.

**BILLING GUIDELINES**

Products that have not received coding verification from PDAC must be coded A9270.

Speech generating device and accessories (e.g., operating system, Word core software, battery charger, mounting plate, built-in stand, vocabulary software, USB cable, one battery pack and a standard one year warranty) are included with the initial placement of the device and is not reimbursed separately.
Accessories not included in initial placement (e.g., cables, battery pack, carrying case, and picture communication symbols (PCS) may be billed separately.

Software (E2511) 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.

**ACCESSORIES**

Accessories (E2599) for E2500 - E2510 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.

**DISPENSING SUPPLIES**

The Health Plan is following Medicare guidelines for supplies provided on reoccurring basis.

Providers are required to contact members prior to dispensing supplies and or medications and not automatically ship supplies. Contact with member must not take place prior to 14 calendar days of delivery and delivery is to be no sooner than 10 calendar days of end of usage. Please refer to CMS Program Integrity Manual for more information. (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

**KX, GA, and GZ MODIFIERS**

Suppliers may submit a claim with a KX modifier only if all the criteria for that item are met.

If the coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, 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.

**ADVANCED BENEFICIARY NOTICE**

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

**NOTE:** Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

**PRICING, DATA ANALYSIS, AND CODING (PDAC)**

The Health Plan has implemented use of Medicare’s PDAC contractor for review of authorizations. Suppliers should contact the PDAC contractor for guidance on the correct coding of these items. dmepdac.com/

When codes E2511-E2599 are requested, the provider must include the manufacturer name and the product name/number with precertification.
**MEDICARE DEFINITIONS AND DESCRIPTION**

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

Code E2511 is used to code for speech generating software program that enables a laptop computer, desktop computer or PDA to function as an SGD. (Within this policy, the term SGD also describes these speech generating software programs). 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 that is billed with codes E2500, E2502 - 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 access device (E2599). E2511 is used for upgrade programs for a computer or PDA that are provided after the initial provision of the software.

Mounting systems (E2512) are accessories that are needed to place the SGD, switches or other access devices within the reach of the member. Code E2599 is used for other separately payable accessories for speech generating devices. Examples include:

- An access device that enables the selection of letters, words, or symbols via direct or indirect selection techniques. Access devices include, but are not limited to, optical head pointers, joysticks, switches, and scanning devices. However, 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 should be included in the charge for the access device itself.

- Replacement accessories such as batteries, battery chargers, and AC adapters.
- Upgrade software programs for E2500, E2502 - E2506, E2508, or E2510 devices that are provided after the initial provision of the SGD.
- Electronic components that allow the SGD to be operated by the drive control interface of a power wheelchair.

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**INTERNET LINKS AND SOURCES**


The Health Plan Provider Procedural Manual. Payment Voucher, Section 14, Page 11

Section 6407 of the Affordable Care Act (ACA) Established a Face-to-Face encounter Requirement for Certain Items of DME


Noridian Healthcare Solutions PDAC. Medicare Pricing Data Analysis and Coding. Advisory Articles. dmepdac.com/resources/advisory_articles.html

General Announcements for Noridian PDAC. Speech Generating Device: Information Required for Coding Verification Review. Email sent 7/29/14 at 5:12 pm. From: Noridian PDAC Updates [pdac@noridian.com]


West Virginia State Plan references audiology, hearing aid, speech, and language services at sections 3.1-A(11), 3.1-B(11), supplement 2 to attachments 3.1-A and 3.1-B(11)(a) and (b) and reimbursement at 4.19-B(11). Attachment 3.1-L addresses benefits for the adult expansion population under the alternative benefits