Speech Generating Devices (NCD 50.1)

Guideline Number: MPG289.06
Approval Date: December 9, 2020

Overview
Speech generating devices are considered to fall within the durable medical equipment (DME) benefit category established by §1861(n) of the Social Security Act. They are covered for patients who suffer from a severe speech impairment and have a medical condition that warrants the use of a device based on the following definitions.

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 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 audible/verbal speech.

Other covered features of the device include the capability to generate email, text, or phone messages to allow the patient to “speak” or communicate remotely, as well as the capability to download updates to the covered features of the device from the manufacturer or supplier of the device.

If a speech generating device is limited to use by a patient with a severe speech impairment and is primarily used for the purpose of generating speech, it is not necessary for the device to be dedicated only to audible/verbal speech output to be considered DME. Computers and tablets are generally not considered DME because they are useful in the absence of an illness or injury.
National Non-Covered Indications

Internet or phone services or any modification to a patient’s home to allow use of the speech generating device are not covered by Medicare because such services or modifications could be used for non-medical equipment such as standard phones or personal computers. In addition, 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 are not covered. This would include any computing hardware or software not necessary to allow for generation of audible/verbal speech, email, text or phone messages, such as hardware or software used to create documents and spreadsheets or play games or music, and any other function a computer can perform that is not directly related to meeting the functional speaking communication needs of the patient, including video communications or conferencing. These features of a speech generating device do not fall within the scope of § 1861(n) of the Social Security Act and the cost of these features are the responsibility of the beneficiary.

Notes:

A speech generating device (SGD) (E2500 - E2511) is covered when all of the following seven bulleted criteria are met:

- Prior to the delivery of the SGD, the beneficiary has had a formal evaluation of his/her cognitive and communication abilities by a speech-language pathologist (SLP). The formal, written evaluation must include, at a minimum, the following elements:
  - Current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of the impairment;
  - An assessment of whether the individual's daily communication needs could be met using other natural modes of communication;
  - A description of the functional communication goals expected to be achieved and treatment options;
  - Rationale for selection of a specific device and any accessories;
  - Demonstration that the beneficiary possesses a treatment plan that includes a training schedule for the selected device;
  - The cognitive and physical abilities to effectively use the selected device and any accessories to communicate;
  - 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

- The beneficiary’s medical condition is one resulting in a severe expressive speech impairment; and
- The beneficiary’s speaking needs cannot be met using natural communication methods; and
- Other forms of treatment have been considered and ruled out; and
- The beneficiary’s speech impairment will benefit from the device ordered; and
- 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
- 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 seven bulleted SGD coverage criteria is not met, the SGD will be denied as not reasonable and necessary.

Codes for SGD E2500-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. Upgrades to speech generating devices and/or software programs that are provided within the five (5) year useful lifetime of the device will be denied as statutorily non-covered.

Accessories

Claims for accessories to SGDs must meet the general coverage requirements for the base SGD described in the seven bulleted criteria addressed above. Claims for SGD accessories for beneficiaries who do not meet the seven bulleted criteria 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.

**Modifiers**

KX Modifier:
Suppliers must add a KX modifier to codes for SGD E2500 - E2599 only if all of the coverage criteria as referenced above have been met, and evidence of such is retained in the supplier’s files and available upon request.

**Applicable Codes**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS 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>
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<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>
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<tr>
<td>E2504</td>
<td>Speech generating device, digitized speech, using prerecorded messages, greater than 20 minutes but less than or equal to 40 minutes recording time</td>
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<tr>
<td>E2506</td>
<td>Speech generating device, digitized speech, using pre-recorded messages, greater than 40 minutes recording time</td>
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<td>E2508</td>
<td>Speech generating device, synthesized speech, requiring message formulation by spelling and access by physical contact with the device</td>
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<td>E2510</td>
<td>Speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access</td>
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<td>E2511</td>
<td>Speech generating software program, for personal computer or personal digital assistant</td>
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<td>E2512</td>
<td>Accessory for speech generating device, mounting system</td>
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<tr>
<td>E2599</td>
<td>Accessory for speech generating device, not otherwise classified</td>
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<th>Modifier</th>
<th>Description</th>
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<td>KX</td>
<td>Requirements specified in the medical policy have been met</td>
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**References**

**CMS National Coverage Determinations (NCDs)**

*NCD 50.1 Speech Generated Devices*
CMS Local Coverage Determinations (LCDs) and Articles

<table>
<thead>
<tr>
<th>LCD</th>
<th>Article</th>
<th>Contractor</th>
<th>DME MAC</th>
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<tr>
<td>L33739 Speech Generating Devices (SGD)</td>
<td>A52469 Speech Generating Devices (SGD) - Policy Article</td>
<td>CGS</td>
<td>CGS: AL, AR, CO, FL, GA, IL, IN, KY, LA, MS, MI, MN, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV</td>
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<td>A52469 Speech Generating Devices (SGD) - Policy Article</td>
<td>Noridian</td>
<td>Noridian: AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MO, MA, MD, ME, MP, MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA, WY</td>
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<td>A55426 Standard Documentation Requirements for All Claims Submitted to DME MACs</td>
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CMS Benefit Policy Manual

Chapter 15 Covered Medical and Other Health Services

CMS Claims Processing Manual

Chapter 20 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

CMS Transmittal(s)

Transmittal 4027, Change Request 10604, Dated 04/27/2018 (Inexpensive or Routinely Purchased Durable Medical Equipment (DME) Payment Classification for Speech Generating Devices (SGD) and Accessories)

MLN Matters

Article MM8304, Detailed Written Orders and Face-to-Face Encounters
Article MM9281, Update to Pub. 100-03, National Coverage Determination Manual, Chapter 1, Part 1, Section 50.1 Speech Generating Device

Other(s)

Durable Medical Equipment, Reference List (NCD 280.1), CMS Website
Medicare National Coverage Determinations Manual (IOM 100-03), Chapter 1, Part 1, Section 50.1

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Summary of Changes</th>
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<tr>
<td>04/01/2021</td>
<td>Template Update</td>
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<tr>
<td></td>
<td>• Reformatted policy; transferred content to new template</td>
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<tr>
<td>12/09/2020</td>
<td>Supporting Information</td>
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<tr>
<td></td>
<td>• Updated References section to reflect the most current information; no change to guidelines</td>
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<td></td>
<td>• Archived previous policy version MPG289.05</td>
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Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

• Medicare coding or billing requirements, and/or
• Medical necessity coverage guidelines; including documentation requirements.
UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

### Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an “AS IS” basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member’s benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.