

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-03 Medicare National Coverage Determinations</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 184</b>	<b>Date: August 21, 2015</b>
	<b>Change Request 9281</b>

**SUBJECT: Update to Pub. 100-03, National Coverage Determination Manual, Chapter 1, Part 1, Section 50.1 Speech Generating Device**

**I. SUMMARY OF CHANGES:** This Change Request (CR) provides updates to add a revised scope of benefit national coverage determination for speech generating devices (SGDs) covered under the Medicare benefit category for Durable Medical Equipment (DME).

**EFFECTIVE DATE: July 29, 2015**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: September 21, 2015**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	1/1/50.1 Speech Generating Devices

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Business Requirements  
Manual Instruction**

# Attachment - Business Requirements

Pub. 100-03	Transmittal: 184	Date: August 21, 2015	Change Request: 9281
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**SUBJECT: Update to Pub. 100-03, National Coverage Determination Manual, Chapter 1, Part 1, Section 50.1 Speech Generating Device**

**EFFECTIVE DATE: July 29, 2015**

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**IMPLEMENTATION DATE: September 21, 2015**

## I. GENERAL INFORMATION

**A. Background:** This Change Request (CR) updates Pub. 100-03, Medicare National Coverage Determinations Manual, chapter 1, part 1, section 50.1 to add a revised scope of benefit national coverage determination for speech generating devices (SGDs) covered under the Medicare benefit category for Durable Medical Equipment (DME).

**B. Policy:** This Change Request (CR) updates Pub.100-03, Medicare National Coverage Determinations Manual, chapter 1, part 1, section 50.1 Speech Generating Devices. This change instructs contractors to update their Local Coverage Determinations (LCDs) and other policy related articles (PAs). Also, this change shall be effective for claims with dates of service on or after July 29, 2015.

## II. BUSINESS REQUIREMENTS TABLE

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C S	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
9281.1	Contractors shall be aware of updates to Pub. 100-03, Medicare National Coverage Determinations Manual, chapter 1, part 1, section 50.1 Speech Generating Devices.	X	X	X	X						
9281.1.1	Contractors shall update their Local Coverage Determinations (LCDs) and other policy related articles (PAs) in accordance with revised Pub. 100-03, Medicare National Coverage Determinations Manual, chapter 1, part 1, section 50.1 Speech Generating Devices.	X	X	X	X						
9281.2	Contractors shall implement the updated coverage policy for speech generating devices issued in Pub. 100-03, Medicare National Coverage Determinations Manual, chapter 1, part 1, section 50.1 Speech Generating Device using existing claims edits as	X	X	X	X						

Number	Requirement	Responsibility								
		A/B MAC			D M E	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
	appropriate.									

### III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H		
9281.3	MLN Article: A provider education article related to this instruction will be available at <a href="http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/">http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X	X	X	

### IV. SUPPORTING INFORMATION

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: All other recommendations and supporting information: N/A**

### V. CONTACTS

**Pre-Implementation Contact(s):** Anita Greenberg, [Anita.Greenberg@cms.hhs.gov](mailto:Anita.Greenberg@cms.hhs.gov)

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

### VI. FUNDING

**Section A: For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**ATTACHMENTS: 0**

# Medicare National Coverage Determinations Manual

## Chapter 1, Part 1 (Sections 10 – 80.12)

### Coverage Determinations

#### 50.1 - Speech Generating Devices

*(Rev.184, Issued: 08-21-15, Effective: 07-29-15, Implementation: 09-21-15)*

##### A. General

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.*

##### B. Nationally Covered Indications

N/A

##### C. Nationally 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. Suppliers of speech generating devices are encouraged to furnish the beneficiary with a voluntary Advance Beneficiary Notice (ABN), or similar notice, which informs that these features are not covered and to alert the beneficiary of the expense of these features.*

**D. Other**

*Medicare Administrative Contractors acting within their respective jurisdictions have discretion to cover or not cover speech generating devices based on their individual reasonable and necessary determinations.*

*(This NCD last reviewed July 2015.)\_*