

Medicare Coverage Document

National Benefit Category Analyses

Speech Generating Devices

Document Information

Date

11/06/2014

Public Comment Period

04/29/2015 - 05/29/2015

[View Public Comments](#)**Title:** Speech Generating Devices**Issue:**

Effective January 1, 2001, speech generating devices are considered to fall within the durable medical equipment (DME) benefit category defined in section 1861(n) of the Social Security Act (the Act). Speech generating devices are covered if the patient suffers from severe speech impairment and the medical condition warrants the use of a device. Speech generating devices are defined for Medicare coverage purposes to include dedicated speech devices used solely by the individual who has severe speech impairment. Speech generating devices also include software that allows a laptop computer, desktop computer or personal digital assistant (PDA) to function as a speech generating device. Devices that are not considered speech generating devices include devices that are not dedicated speech devices, or devices that are capable of running software for purposes other than for speech generation. The national coverage determination (NCD) is available in section 50.1 of the Medicare NCD Manual (Pub. No. 100-3, Ch. 1, Part 1).

Since 2001, the technology of devices that generate speech and the ways in which the devices are used by patients to meet their medical needs has changed significantly. For example, patients now use speech devices to generate text and email messages for the purpose of communicating with their caregivers and physicians. Therefore, in light of the changes in technology and use of devices that generate speech, we are internally generating a reconsideration of this NCD to address coverage of devices that generate speech as well as other forms of communication.

Benefit Category: Section 1861(n) of the Social Security Act**Requestor Name(s):** Internal**Expected Completion Date:** July 28, 2015**PDM Due Date:** May 1, 2015**Lead Medical Officer(s)**

Dr. Subash Duggirala

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November 6, 2014

CMS opens a benefit category determination NCD process and 30-day public comment period begins.
April 29, 2015

Posted [proposed decision memo](#)
July 29, 2015

Posted [final decision memo](#)

PROPOSED DECISION MEMORANDUM

TO:	Administrative File Speech Generating Devices
FROM:	Laurence Wilson Director, Chronic Care Policy Group
	Joel Kaiser Director, Division of DMEPOS Policy
	Subash Duggirala, MD Lead Medical Officer
SUBJECT:	Proposed Scope of Benefit NCD: Speech Generating Devices
DATE:	April 29, 2015

I. Proposed Decision

The Centers for Medicare and Medicaid Services (CMS) proposes to revise the current scope of benefit national coverage determination (NCD) for speech generating devices at § 50.1 of Chapter 1, Part 1 of the Medicare National Coverage Determinations Manual.

The following is the proposed scope of benefit NCD:

Speech Generating Devices

Speech generating devices are considered to fall within the DME benefit category established by § 1861(n) of the Social Security Act. They are covered for patients who suffer from 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 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 speech output, using prerecorded messages;
- synthesized speech output which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
- synthesized 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 function as a speech generating device.

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.

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 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 Act and the cost of these features are the responsibility of the beneficiary. Although it is not a Medicare requirement, suppliers of speech generating devices are encouraged to furnish the beneficiary with an Advanced Beneficiary Notice (ABN) informing them that these features are not covered by Medicare and so the beneficiary is liable for the expense of these features.

We are requesting public comments to this proposed decision pursuant to § 1862(l) of the Social Security Act (the Act). After consideration of the public comments, we will issue a final determination responding to the public comments consistent with § 1862(l)(3) of the Act.

II. Background and History of Medicare Coverage

Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage. The term “durable medical equipment” (DME) is defined in § 1861(n) of the Social Security Act (the Act) to include iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient’s home, including an institution used as his home other than a hospital meeting the

requirements of § 1861(e)(1) of the Act or a nursing facility meeting the requirements of § 1819(a)(1) of the Act. The term DME is further defined in Medicare regulations at 42 CFR § 414.202 to mean equipment furnished by a supplier or home health agency that: can withstand repeated use; has an expected life of at least 3 years; is primarily and customarily used to serve a medical purpose; generally is not useful to an individual in the absence of an illness or injury; and is appropriate for use in the home. All of these conditions must be met in order to be considered DME under Medicare Part B.

Prior to 2001, the national Medicare coverage policy at § 60-9 of the Medicare Coverage Issues Manual (HCFA-Publication 6 Thru T70) provided that communicators and augmentative and alternative communication devices were convenience items and not primarily medical in nature.

On January 1, 2001, CMS established a national coverage determination recognizing speech generating devices (previously referred to as communicators and augmentative and alternative communication devices) as DME if the Medicare contractor's medical staff determined that the patient suffers from a severe speech impairment and that the medical condition warrants the use of the device. The scope of benefit NCD is located at § 50.1 of chapter 1 of part 1 of the Medicare National Coverage Determinations Manual (CMS-Publication 100-03). Section 50.1 defines speech generating devices as follows:

Speech generating devices are defined as speech aids that provide an individual who has a severe speech impairment with the ability to meet his functional speaking needs. Speech generating devices are characterized by:

- Being a device that generates speech, used solely by the individual who has a severe speech impairment;
- May have digitized speech output, using prerecorded messages, less than or equal to 8 minutes recording time;
- May have digitized speech output, using prerecorded messages, greater than 8 minutes recording time;
- May have synthesized speech output which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
- May have synthesized speech output which permits multiple methods of message formulation and multiple methods of device access; or
- May be software that allows a laptop computer or personal digital assistant (PDA) to function as a speech generating device.

Devices that would not meet the definition of speech generating devices and therefore, do not fall within the scope of section 1861(n) are characterized by:

- Devices that are not dedicated speech devices, but are devices that are capable of running software for purposes other than for speech generation, e.g., devices that can also run a word processing package, an accounting program, or perform other non-medical functions.
- Laptop computers, desktop computers, PDAs, which may be programmed to perform the same function as a speech generating device, are non-covered since they are not primarily medical in nature and do not meet the definition of DME. For this reason, they cannot be considered speech generating devices for Medicare coverage purposes.
- A device that is useful to someone without severe speech impairment is not considered a speech generating device for Medicare coverage purposes.

III. Timeline of Recent Activities

Date	Action
November 6, 2014	CMS opens a benefit category determination NCD process and 30-day public comment period begins.
December 6, 2014	End of public comment period for tracking sheet. CMS received 2,290 comments.

IV. Benefit Category Question and Initial Public Comments

Effective January 1, 2001, speech generating devices are considered DME. We are reconsidering § 50.1 to determine whether devices that allow other forms of communication that generate speech, such as devices that are capable of transmitting written messages, would appropriately fall within the Medicare Part B benefit category for durable medical equipment (DME). We are also reconsidering the general requirement in § 50.1 that devices be dedicated speech generating devices in order to be considered DME.

CMS received 2,290 comments during the 30-day public comment period from November 6, 2014 thru December 6, 2014. The majority of these comments supported coverage of devices that allow other forms of communication other than generation of speech as durable medical equipment. Comments were received from patients and family members, patient advocacy groups and organizations,

manufacturers, speech language pathologists and other clinicians.

The public comments were made available at the following link:

<http://www.cms.gov/medicare-coverage-database/details/mcd-view-public-comments.aspx?MCDId=26&ExpandComments=n&mcdtypename=National+Benefit+Category+Analyses&MCDIndexType=3&bc=AgAEAAAAACAAAA%3d%3d&>

V. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act. § 1869(f)(1)(B), § 1862(l)(6)(A). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, must not be otherwise excluded from coverage, and must be reasonable and necessary as described in section 1862(a)(1)(A) of the Act.

DME is defined in Federal regulations at 42 CFR § 414.202 as equipment furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

We believe that speech generating devices, as defined in the NCD, meet this regulatory definition. An item is considered durable if it can withstand repeated use, i.e., the type of item which could normally be rented and used by successive patients, and although speech generating devices are often programmed to use key words and phrases that a specific patient may commonly use or need to use, the devices can be re-programmed and are rented and used by successive patients.

The requirement in the existing NCD that coverage is limited to patients with severe speech impairment ensures that speech generating devices covered as DME are primarily and customarily used to serve the medical purpose of generating speech and would not be useful in the absence of an illness or injury (the speech impairment).

Finally, we believe that speech generating devices are appropriate for use in the home by patients so that they can communicate while they are in their home.

Under this reconsideration, we are proposing to expand the types and features of speech generating devices that would fall within the DME benefit category. A speech generating device is used by an individual with severe speech impairment to address the underlying medical problem of lack of ability to produce speech. The current NCD focuses primarily on the generation of audible speech communications with someone in close proximity who can hear the speech generated by the device. We believe it is appropriate to broaden coverage under the DME benefit category to cover speech generating devices that allow for more remote speech in the form of both audible and written communications (e.g., the generation of written messages, such as email and text messages, as well as the capability to interface electronically with a telephone to deliver speech via phone messages to individuals not in close proximity to the user of the device). We believe that a written message or phone message from an individual lacking the ability to speak serves the same purpose in communicating with individuals not in close proximity to the patient as generation of speech does in communicating with individuals who are in close proximity to the patient. For example, expressing an urgent need, such as when thirst or pain becomes unbearable, to a caregiver who is not in the home at the time serves the same purpose as expressing the need to a caregiver who is in the home at the time the message needs to be communicated. We do not liken this to the general use of safety or precautionary alert devices for reporting accidents that may or may not happen. An individual with severe speech impairment always needs to communicate regardless of where they are and the person to whom they are communicating is, and therefore, equipment allowing the patient to communicate remotely is not precautionary. As discussed above, speech generating devices, as defined under the NCD, meet the five prong definition for DME. We believe that a device that generates speech for a patient with severe speech impairment and is also capable of generating written messages or phone messages to allow the patient to communicate remotely with individuals still meets the definition of DME.

We also believe the "dedication" requirement may be overly restrictive. As long as the speech generating device is limited to use by patients with severe speech impairment, and is primarily used for the purpose of generating speech, we do not believe it is necessary for a speech generating device to be dedicated only to speech generation in order to be considered DME.

We do not believe, however, that video communications or video conferencing serves the same purpose as speech in terms of delivering a message to an individual and therefore, should not be a covered feature of a speech generating device. A written or phone message is sufficient for communicating speech or language to individuals not in close proximity to the patient and serves the same purpose as generation of speech that is audible for individuals in close proximity to the patient. We do not believe that video conferencing serves the same purpose as speech and should not be a covered feature of a speech generating device.

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, other specific features of a covered device that are not used by the individual who has a severe speech impairment to meet his functional medical communication needs are not covered. This would include any computing hardware or software not necessary to allow for generation of speech or email or text messages, such as hardware or software used to create documents and spreadsheets, play games or music, or any other function a computer can perform that is not directly related to meeting the speaking needs of the patient.

VI. Conclusion

CMS proposes to revise the current scope of benefit NCD for speech generating devices at § 50.1 of Chapter 1, Part 1 of the Medicare National Coverage Determinations Manual.

The following is the proposed scope of benefit NCD:

Speech Generating Devices

Speech generating devices are considered to fall within the 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 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 speech output, using prerecorded messages;
- synthesized speech output which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
- synthesized 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 function as a speech generating device.

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.

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 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 Act and the cost of these features are the responsibility of the beneficiary. Although it is not a Medicare requirement, suppliers of speech generating devices are encouraged to furnish the beneficiary with an Advanced Beneficiary Notice (ABN) informing them that these features are not covered by Medicare and so the beneficiary is liable for the expense of these features.

FINAL DECISION MEMORANDUM

TO:	Administrative File Speech Generating Devices
FROM:	Laurence Wilson Director, Chronic Care Policy Group
	Joel Kaiser Director, Division of DMEPOS Policy
	Crystal Simpson, MD Lead Medical Officer
SUBJECT:	Final Scope of Benefit NCD: Speech Generating Devices
DATE:	July 29, 2015

I. Final Decision

The scope of benefit national coverage determination (NCD) for speech generating devices at §50.1 of Chapter 1, Part 1 of the Medicare National Coverage Determinations Manual is revised to read as follows:

Speech Generating Devices

Speech generating devices are considered to fall within the durable medical equipment 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.

As long as the 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 a speech-generating device to be dedicated only to speech generation to be considered DME. Computers and tablets in general are not considered DME because they are useful in the absence of an illness or injury.

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. Although it is not a Medicare requirement, suppliers of speech generating devices are encouraged to furnish the beneficiary with a voluntary Advance Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131, or similar notice, to inform them that these features are not covered by Medicare and to alert the beneficiary regarding the expense of these features.

II. Background and History of Medicare Coverage

Medicare is a defined benefit program. An item or service must fall within a benefit category as a prerequisite to Medicare coverage. The term “durable medical equipment” (DME) is defined in § 1861(n) of the Social Security Act (the Act) to include iron lungs, oxygen tents, hospital beds, and wheelchairs used in the patient's home, including an institution used as his home other than a hospital meeting the requirements of § 1861(e)(1) of the Act or a nursing facility meeting the requirements of § 1819(a)(1) of the Act. The term DME is further defined in Medicare regulations at 42 CFR § 414.202 to mean equipment furnished by a supplier or home health agency that: can withstand

repeated use; has an expected life of at least 3 years; is primarily and customarily used to serve a medical purpose; generally is not useful to an individual in the absence of an illness or injury; and is appropriate for use in the home. All of these conditions must be met in order to be considered DME under Medicare Part B.

Prior to 2001, the national Medicare coverage policy at § 60-9 of the Medicare Coverage Issues Manual (HCFA-Publication 6 Thru T70) provided that communicators and augmentative and alternative communication devices were convenience items and not primarily medical in nature.

On January 1, 2001, CMS established a national coverage determination recognizing speech generating devices (previously referred to as communicators and augmentative and alternative communication devices) as DME if the Medicare contractor's medical staff determined that the patient suffers from a severe speech impairment and that the medical condition warrants the use of the device. The scope of benefit NCD is located at §50.1 of chapter 1 of part 1 of the Medicare National Coverage Determinations Manual (CMS-Publication 100-03). From January 2001 through July 2015, §50.1 defined speech generating devices as follows:

Speech generating devices are defined as speech aids that provide an individual who has a severe speech impairment with the ability to meet his functional speaking needs. Speech generating devices are characterized by:

- Being a device that generates speech, used solely by the individual who has a severe speech impairment;
- May have digitized speech output, using prerecorded messages, less than or equal to 8 minutes recording time;
- May have digitized speech output, using prerecorded messages, greater than 8 minutes recording time;
- May have synthesized speech output which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
- May have synthesized speech output which permits multiple methods of message formulation and multiple methods of device access; or
- May be software that allows a laptop computer or personal digital assistant (PDA) to function as a speech generating device.

Devices that would not meet the definition of speech generating devices and therefore, do not fall within the scope of section 1861(n) are characterized by:

- Devices that are not dedicated speech devices, but are devices that are capable of running software for purposes other than for speech generation, e.g., devices that can also run a word processing package, an accounting program, or perform other non-medical functions.
- Laptop computers, desktop computers, PDAs, which may be programmed to perform the same function as a speech generating device, are non-covered since they are not primarily medical in nature and do not meet the definition of DME. For this reason, they cannot be considered speech generating devices for Medicare coverage purposes.
- A device that is useful to someone without severe speech impairment is not considered a speech generating device for Medicare coverage purposes.

III. Timeline of Recent Activities

Date	Action
November 6, 2014	CMS opens a benefit category determination NCD process and 30-day public comment period begins.
December 6, 2014	End of public comment period for tracking sheet. CMS received 2,290 comments.
April 29, 2015	CMS posts the proposed decision memorandum for 30 days of public comment.
May 29, 2015	The public comment period on the proposed decision memorandum closes with 226 comments received.

IV. Benefit Category Question and Initial Public Comments

As part of the NCD process, CMS uses initial public comments to obtain information regarding the topic under study. CMS received 2,290 comments during the 30-day public comment period from November 6, 2014 thru December 6, 2014. The majority of these comments supported coverage of devices that allow other forms of communication other than generation of speech as durable medical equipment. Comments were received from patients and family members, patient advocacy groups and organizations, manufacturers, speech language pathologists and other clinicians. These comments are available on the CMS website at:

<http://www.cms.gov/medicare-coverage-database/details/mcd-view-public-comments.aspx?MCDId=26&ExpandComments=n&bc=AAAAAAAAACAAAA%3d%3d&>

A summary of the public comments on the initial tracking sheet and responses to these comments are provided below.

Public Comment on the Tracking Sheet: 11/06/2014- 12/06/2014

Comment

Several commenters believed that Medicare should continue to cover computers that are modified to become SGDs.

Response

We agree that computers that are modified to generate speech can be considered SGDs if the device is used primarily by a patient with severe speech impairment for the primarily purpose of generating speech. This decision was reflected in the proposed NCD.

Comment

Many commenters expressed a strong opinion that SGDs covered by Medicare should have the capability to perform other tasks and should not be dedicated to only generating speech.

Response

We agree with this comment and this decision was reflected in the proposed NCD.

Comment

Many commenters felt that the ability to generate written text or email messages and phone messages should be a covered feature of an SGD.

Response

We agree with this comment and this decision was reflected in the proposed NCD.

Comment

Many commenters felt that the ability to send video transmissions or to conduct video conferencing should be a covered feature of an SGD.

Response

As explained in more detail below, we do not agree that video conferencing is a necessary form of speech for purposes of this NCD.

Comment

Some commenters felt that environmental controls (e.g., turning lights on and off in the home) should be a covered feature of an SGD.

Response

We do not agree. Environmental controls are not necessary to generate speech.

Comment

Some commenters stated that Medicare coverage should continue for speech generating software used on non-covered computers and tablets.

Response

We agree with this comment and this decision was reflected in the proposed NCD.

Public Comment on the Proposed Decision: 04/29/2015- 05/29/2015

CMS received 226 comments in response to the proposed decision memorandum.

Comment

Most of the 226 comments expressed strong support for the proposed decision.

Response

We appreciate the support from the commenters on the proposed decision.

Comment

Several commenters indicated that the terminology "functional speaking" or "functional speaking communication" is not recognized within the profession, nor is it consistent with the inclusion of email in the proposed NCD. The commenters recommend use of "functional communication" in lieu of "functional speaking communication" because candidates for SGDs have lost the ability to use speech to meet their functional and medical communication needs. The commenters added that this change would not change the meaning of the statement or expand coverage, and is consistent with the use of the SGD for both speech generation and email purposes.

Response

We appreciate and have considered the commenters' suggested change but have determined that use of the word "communication" could be confusing in terms of Medicare coverage of devices that generate "speech." The DME benefit and definition addresses equipment that are used for a medical purpose, and in this case of the speech generating device NCD, the medical purpose is to address "speech impairment."

Speech generating devices allow the beneficiary the ability to "speak," which we believe may include certain forms of communication (email, text, phone messages) that also allow the beneficiary to "speak," particularly with individuals who are not in close proximity to the patient. However, not all forms of communication constitute speech under this NCD. For example, we do not believe that video communication, or transmitting pictures along with audible speech remotely to someone who is not in close proximity to the patient, constitutes speech for purposes of this NCD. While transmission of audible speech is necessary to replace a person's ability to speak, we do not believe a video image is.

Comment

Several commenters stated that they do not agree that video communications or video conferencing or communications do not serve the same purpose as speech in terms of delivering a message to an individual. The commenters expressed concerns that lack of coverage for video conferencing could interfere with patient access to telemedicine services.

Response

We appreciate and have considered the commenters' arguments but continue to believe that video communications or video conferencing do not serve the same purpose as audible/verbal speech in terms of delivering a message to an individual, and therefore, are not considered covered features of a speech generating device. A written or phone message is sufficient for communicating speech or language to individuals not in close proximity to the patient, including the patient's physician, and serves the same purpose as generation of speech that is audible for individuals in close proximity to the patient. Video includes other aspects e.g., visual which are not necessary to convey a message; typically such a feature is not needed in regards to audible/verbal speech. We do not believe it is necessary for any beneficiary to see a person or project an image of themselves to communicate with another person.

Comment

Numerous commenters expressed support for the proposed NCD in terms of expanding the definition of SGD and eliminating the requirement that devices must be dedicated to only generating speech in order to be considered SGDs. Several commenters also recommend that the following sentence from the analysis portion of the proposed decision memorandum be added to the text of the NCD: "As long as the 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 a speech-generating device to be dedicated only to speech generation to be considered DME." Commenters felt that this would help reinforce and clarify the change in removing the requirement that devices be dedicated to generating speech only.

Response

We appreciate the support from the commenters on the proposed decision. We agree with this comment to add this sentence to the text of the NCD and have made the suggested change.

Comment

Several commenters felt that the word "voluntary" should be added prior to "Advance Beneficiary Notice of Noncoverage (ABN)" in the section of the proposed NCD related to notifying beneficiary's that they are responsible for the cost of non-covered features of an SGD. Alternatively, commenters felt that the term "Advance Beneficiary Notice of Noncoverage" should be replaced with the term "notice" to prevent confusion from the contractors, suppliers, and patients regarding when use of an ABN is required.

Response

We agree with these comments and have revised the NCD based on these suggestions.

Comment

Several commenters felt that Medicare should cover computer tablets and similar devices used in conjunction with speech generating applications because they are less expensive and are preferred by certain patients.

Response

We appreciate and have considered the commenters' arguments, but we do not agree that computers and tablets can be covered as DME under the Medicare program. Computers and tablets are not primarily used for a medical purpose and are useful in the absence of an illness or injury and therefore, do not meet the definition of DME. In the revised NCD we are maintaining coverage of speech generating software for use on computers, tablets, and other devices, but the computers and tablets are not DME and non-covered. We will further clarify this point in the NCD.

Comment

One commenter recommended that the phrase "speech aids" be included in the definition of SGD: "speech generating devices are speech aids considered to fall within the DME benefit category..." The commenter believed that the addition of this phrase may be beneficial to individuals with insurance other than Medicare.

Response

We agree with this comment and will add the phrase "speech aids" in the definition of SGD.

Comment:

Some commenters requested CMS to add the following to the NCD: Reasonable and necessary accessories for speech-generating devices include accessing technology and mounting accessories used by patients with limited mobility. These accessories include, but are not limited to: eye-tracking/gazing, switches, pointers, scanners, and table or wheelchair mounting hardware.

Response:

We appreciate and have considered the commenters' arguments, but these comments relate specifically to whether certain accessories are reasonable and necessary for the effective use of SGDs and are outside the scope of this NCD. CMS did not propose to establish an NCD addressing medical necessity of specific accessories used with SGDs. We do note however that the recently passed Steve Gleason Act of 2015 amends the definition of DME in the statute to include "eye tracking and gaze interaction accessories for speech generating devices furnished to individuals with a demonstrated medical need for such accessories."

Comment:

Some commenters requested that CMS continue exploring removing the 13-month capped rental payment method for SGDs. One commenter indicated there continues to be uncertainty by beneficiaries and suppliers as to whether the NCD will apply to items furnished during the capped rental period, as well as after ownership of the SGD transfers to the beneficiary following 13 months of continuous use. The commenter stated it would be helpful to insert a statement in the NCD regarding application to both rental and owned SGDs.

Response:

We appreciate and have considered the commenters' arguments, but the Medicare payment methodology for SGDs are outside the scope of Medicare coverage under this NCD. We do note however that the recently passed Steve Gleason Act of 2015 amends the statute to move SGDs and accessories needed to effectively utilize an SGD from the capped rental payment class to the payment class for inexpensive and other routinely purchased DME for items furnished from October 1, 2015, through September 30, 2018.

Comment

One commenter suggested that the language regarding coverage of a device with the capability to generate email be modified to clarify that the capability of the device to access the internet or other communication networks is covered. Some commenters suggested that coverage should be provided for access to social networks available through the internet such as Facebook and chat rooms.

Response

We appreciate and have considered the commenters' arguments, but we do not agree with these comments. Coverage is limited to the capability to generate email messages, text messages, or phone messages. The capability to access the internet to perform other tasks is not necessary for generating speech and could be useful in the absence of an illness or injury, so access to the internet and other communication networks, in general, is not a covered feature of an SGD. Coverage is limited to whatever capability is necessary to generate emails, which may include access to the internet for the purpose of sending email messages, but access to the internet in general is not a covered feature of an SGD. Therefore, such a general statement is not appropriate for the NCD.

Comment

Some commenters stated that Medicare should not pay for internet services that patients already pay for as part of their home utilities.

Response

We agree and made this clear in the proposed and final NCD.

Comment

Some commenters suggested that Medicare should cover other capabilities of computer hardware and software needed by patients with medical condition who cannot otherwise access computers to perform various functions such as creating documents and spreadsheets, playing games, or listening to music.

Response

We appreciate and have considered the commenters' arguments, but such features are not necessary to meet functional speech needs; therefore, we do not agree with these suggestions.

Comment

Some commenters stated that Medicare should cover environmental control features of an SGD such as turning on lights.

Response

We appreciate and have considered the commenters' arguments, but such assistive technology is not necessary for the generation of speech.

Comment

Some commenters indicated that the HCPCS codes for SGDs need to be updated to reflect current technology.

Response

While we appreciate these comments, they are outside the scope of this NCD. Requests for changes to the HCPCS can be submitted using the public process outlined on CMS.gov at:

http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Application_Form_and_Instructions.html

Comment

Some commenters stated that the option for coverage of speech generating software should be maintained.

Response

We agree and made this clear in the final NCD.

Comment

Numerous other comments were outside the scope of this NCD.

Response

We appreciate and have considered the commenters' arguments, but we are not responding to these comments since they are outside the scope of this NCD.

Public comments may be viewed using the following link:

<http://www.cms.gov/medicare-coverage-database/details/mcd-view-public-comments.aspx?MCDId=26>

V. CMS Analysis

National coverage determinations (NCDs) are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally under title XVIII of the Social Security Act. § 1869(f)(1)(B), § 1862(l)(6)(A). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, must not be otherwise excluded from coverage, and must be reasonable and necessary as described in section 1862(a)(1)(A) of the Act.

DME is defined in Federal regulations at 42 CFR § 414.202 as equipment furnished by a supplier or a home health agency that meets the following conditions:

- (1) Can withstand repeated use.
- (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
- (3) Is primarily and customarily used to serve a medical purpose.
- (4) Generally is not useful to an individual in the absence of an illness or injury.
- (5) Is appropriate for use in the home.

We believe that speech generating devices, as defined in the NCD, meet this regulatory definition. An item is considered durable if it can withstand repeated use, i.e., the type of item which could normally be rented and used by successive patients, and although speech generating devices are often programmed to use key words and phrases that a specific patient may commonly use or need to use, the devices can be re-programmed and are rented and used by successive patients.

The requirement in the NCD that coverage is limited to patients with severe speech impairment ensures that speech generating devices covered as DME are primarily and customarily used to serve the medical purpose of generating speech and would not be useful in the absence of an illness or injury (the speech impairment).

Finally, we believe that speech generating devices are appropriate for use in the home by patients so that they can communicate while they are in their home.

Under this revised NCD, we are expanding the types and features of speech generating devices that would fall within the DME benefit category. A speech generating device is used by an individual with severe speech impairment to address the underlying medical problem of lack of ability to produce speech. The previous NCD focused primarily on the generation of audible speech communications with someone in close proximity who can hear the speech generated by the device. We believe it is appropriate to broaden coverage under the DME benefit category to cover speech generating devices that allow speech in the form of both audible and written communications (e.g., the generation of written messages, such as email and text messages, as well as the capability to interface electronically with a telephone to deliver speech via phone messages to individuals, particularly those individuals not in close proximity to the user of the device). We believe that a written message or phone message from an individual lacking the ability to speak serves the same purpose in communicating with individuals as generation of audible/verbal speech. For example, expressing an urgent need, such as when thirst or pain becomes unbearable, to a caregiver who is not in the home at the time serves the same purpose as expressing the need to a caregiver who is in the home at the time the message needs to be communicated. We do not liken this to the general use of safety or precautionary alert devices for reporting accidents that may or may not happen. An individual with severe speech impairment always needs the ability to replace speech to communicate regardless of where they are and the person to whom they are communicating is, and therefore, equipment allowing the patient to communicate remotely is not precautionary. As discussed above, speech generating devices, as defined under the NCD, meet the five prong definition for DME. We believe that a device that generates speech for a patient with severe speech impairment and is also capable of generating written messages or phone messages to allow the patient to communicate remotely with individuals still meets the definition of DME.

We also believe the "dedication" requirement is overly restrictive. As long as the speech generating device is limited to use by patients with severe speech impairment, and is primarily used for the purpose of generating speech, we do not believe it is necessary for a speech generating device to be dedicated only to speech generation in order to be considered DME.

We continue to believe that video communications or video conferencing are not necessary forms of speech. A written or phone message communicates speech or language (i.e., words) to individuals and serves the same purpose as generation of speech that is audible for individuals in close proximity to the patient. Transmitting an image of a person to another individual is not sending speech or words to the individual.

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, other specific features of a covered device that are not used by the individual who has a severe speech impairment to meet his functional medical communication needs are not covered. This would include any computing hardware or software not necessary to allow for generation of speech or email or text messages, such as hardware or software used to create documents and spreadsheets, play games or music, or any other function a computer can perform that is not directly related to meeting the speaking needs of the patient.

Finally, we are making a few technical changes to the proposed NCD including the deletion of the word "so" which was a typographical error and use of the phrase "audible/verbal" in several places before the word "speech" to differentiate audible/verbal speech from other forms of speech or communication such as email, text, or phone messages. We are also making changes, as noted above, in response to suggestions made by commenters.

VI. Conclusion

The scope of benefit national coverage determination (NCD) for speech generating devices at §50.1 of Chapter 1, Part 1 of the Medicare National Coverage Determinations Manual is revised to read as follows:

Speech Generating Devices

Speech generating devices are considered to fall within the durable medical equipment 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.

As long as the 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 a speech-generating device to be dedicated only to speech generation to be considered DME. Computers and tablets in general are not considered DME because they are useful in the absence of an illness or injury.

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. Although it is not a Medicare requirement, suppliers of speech generating devices are encouraged to furnish the beneficiary with a voluntary Advance Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131, or similar notice, to inform them that these features are not covered by Medicare and to alert the beneficiary regarding the expense of these features.

