



Medical Coverage Policy

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Speech Generating Devices

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Related Coverage Resources

[Autism Spectrum Disorders/Pervasive Developmental Disorders: Assessment and Treatment Speech Therapy](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses speech generating devices which assist individuals with severe speech impairments with the ability to meet functional speaking needs..

Coverage Policy

Coverage for speech generating devices varies across plans. Refer to the customer’s benefit plan document for coverage details.

Many benefit plans exclude coverage for “aids or devices that assist with nonverbal communications”. When this language is present in the benefit plan, speech generating devices that use prerecorded messages (HCPCS codes E2500-E2506) are not covered. However, unless specifically excluded, speech generating devices that use synthesized speech are covered if criteria are met.

When covered, coverage for speech generating devices is subject to the terms, conditions and limitations of the applicable benefit plan’s Durable Medical Equipment (DME) benefit and schedule of copayments.

If coverage for the specific speech generating device is available, the following conditions of coverage apply.

Covered Speech Generating Devices:

A speech generating device is generally limited to a device that uses synthesized speech. The following speech generating devices are considered medically necessary when the criteria outlined below are met:

HCPCS Codes	Description
E2508	Speech generating device, synthesized speech, requiring message formulation by spelling and access by physical contact with the device
E2510	Speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access

A speech generating device that utilizes synthesized speech (HCPCS codes E2508, E2510) is considered as medically necessary DME when ALL of the following criteria are met:

- The individual has a permanent and severe expressive speech impairment such as dysarthria, anarthria, aphasia, or aphonia, including a severe speech impairment associated with an autism spectrum disorder or pervasive developmental disorders.
- A speech evaluation, conducted by a speech-language pathologist, has documented the severity of the individual’s disability, specific to their primary language.
- Speaking needs cannot be met using natural communication methods.
- Other forms of treatment have failed, are contraindicated, or are otherwise not appropriate.
- A speech generating device is available in the individual’s primary language and is being requested for the sole purpose of speech generation.
- The speech generating device is used primarily for speech, but may also include the following:
 - the capability to generate email, text, or phone messages which allows the individual to communicate remotely
 - the capability to download updates to the covered features of the device from the manufacturer or supplier of the device

Speech Generating Devices Accessories

A speech generating device accessory (HCPCS codes E2512, E2599) is considered medically necessary for a speech generating device when the medical necessity for the speech generating device is met.

Speech Generating Devices with Pre-recorded Messages:

A Speech generating device that uses pre-recorded messages is specifically excluded under standard benefit plans.

Speech generating devices with pre-recorded messages include the following:

HCPCS Codes	Description
E2500	Speech generating device, digitized speech, using pre-recorded messages, less than or equal to 8 minutes recording time
E2502	Speech generating device, digitized speech, using pre-recorded messages, greater than 8 minutes but less than or equal to 20 minutes recording time
E2504	Speech generating device, digitized speech, using pre-recorded messages, greater than 20 minutes but less than or equal to 40 minutes recording time
E2506	Speech generating device, digitized speech, using pre-recorded messages, greater than 40 minutes recording time

The following are considered not medical in nature, and thus are considered not medically necessary:

- multi-purpose, general consumer electronic devices such as personal digital assistants (PDAs), computers, tablet devices (e.g., iPads), smart phones, electronic mail devices and pagers, because they are not medical in nature.
- features of a speech generating device that are not used to meet functional speaking or communication needs, including but not limited to:
 - computing hardware or software not necessary to allow for generation of audible/verbal speech, email, text or phone messages
 - hardware or software used to create documents and spreadsheets, play games or music, video communications or video conferencing

General Background

Speech generating devices (SGDs) assist individuals with severe speech impairments with the ability to meet their functional speaking needs. A SGD may also be considered an electronic augmentative and alternative communication device that generates speech output. Augmentation and alternative communication involves the attempt to compensate for the impairments of individual with severe expressive speech impairment.

Speech is the articulation and phonation of language sounds. Language refers to symbolic communication and is the ability to converse, comprehend, repeat, read, and write. Communication disorders may include (Bradley, et al., 2008; National Institute on Deafness and Other Communication Disorders [NIDCD]):

- Dysarthria: This disorder involves the abnormal articulation of sounds or phonemes. This group of speech disorders is caused by disturbances in the strength or coordination of the muscles of the speech mechanism as a result of damage to the brain or nerves.
- Apraxia: The disorder stems from a deficit in the planning and programming of the sequence of movements for speech and occurs despite the fact that the same muscles move normally when speech is not involved. The most common cause is stroke; however, apraxia may also occur with tumor or traumatic brain injury.
- Aphasia: This is the impairment of an individual's ability to understand and formulate language. Aphasia results from brain damage, typically involving the language-dominant (i.e., left) cerebral hemisphere. This disorder is a total or partial loss of the ability to use or understand language; usually caused by stroke, brain disease, or injury.
- Anarthria: This disorder is a total loss of ability to articulate.

SGDs have been divided into these technologically and clinically distinct categories:

- SGD with digitized speech output
- SGD with synthesized speech output, includes these two types:
 - devices which requires message formulation by spelling and device access by physical contact, with direct-selection techniques
 - devices which permits multiple methods of message formulation and multiple methods of device access

The devices vary in the features found in each. The features may include:

- methods of displaying language/message components: this may include dynamic or static display
- methods of storing and retrieving language: this includes the levels and encoding strategies utilized (e.g., numeric, letter, semantic)
- rate enhancing method (e.g., message prediction)

Digitized speech devices utilize words or phrases that have been recorded by an individual other than the SGD user for playback upon command of the SGD user. They are also referred to as devices with whole message speech output.

Unlike the prerecorded messages of digitized speech, synthesized speech technology translates a user's input into device-generated speech. Users of synthesized speech devices are not limited to prerecorded messages but rather can independently create messages as their communication needs dictate. These devices require that the user make physical contact with a keyboard, touch screen or other display containing an alphanumeric display.

Synthesized speech devices permit the user multiple methods of message formulation and multiple methods of 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 methods: direct physical contact via a keyboard or touch screen, or indirect selection techniques via a specialized access device such as a joystick, a head-mouse, an optical head-pointer, a switch, a light pointer, an infrared pointer, a scanning device, or Morse code.

Speech generating software programs enable a devices such as laptop computer, desktop computer, personal digital assistant (PDA), tablet devices (e.g., iPads), or smart phones to function as an SGD. In the context of this Coverage Policy, an SGD pertains to the speech generating software programs only (i.e., HCPCS code E2511). This does not include the software that is included in the provision of a SGD.

Personal digital assistants (PDAs) are handheld devices that integrate the functions of a small computer with features such as a cell phone, personal organizer, electronic mail or pager. Information may be entered either via a pen-based system using a stylus and handwriting recognition software, or via a keyboard, or it may be downloaded from a personal computer using special cables and software. These devices, including, but not limited to, PDAs, computers, tablet devices (e.g., iPads), smart phones, electronic mail devices and pagers are not used for the sole purpose of speech generation, are not considered to be speech generating devices and not medical in nature.

Accessories for speech generating devices (i.e., HCPCS code E2512, E2599) may be necessary for an individual to use a device. The medical necessity of these accessories should be clearly indicated as part of the speech-language evaluation. The selection of accessories is determined by the speech-language pathologist (SLP) and as necessary by an occupational therapist and is based on the user's physical capabilities, including motor skills and visual abilities. The accessories should be critical to the proper functioning and maintenance of the device and should not be for the comfort or convenience of the individual. Many of the accessories are used by individuals with neurological conditions to enable them to use the device. Accessories for speech generating devices (i.e., HCPCS code E2512, E2599) include, but are not limited to:

- Access devices (HCPCS code E2599) that enable direct or indirect selection of letters, words or symbols via direct or indirect selection techniques:
 - Non-electronic devices include: pointers (head and foot), splints, mouth stick, and keyguards which enable the use of the keyboard for an individual who has difficulty using a standard keyboard
 - electronic (direct) devices include: infrared pointers, light pointers, eye-gaze systems, joysticks, optical head pointers, head controlled mice
 - electronic (indirect) devices include: pneumatic switch, rocking lever switch, tread switch
- Ocular tracking device, any type, describes an SGD accessory used with an SGD or SGD software to allow a speech-impaired person to use his or her eyes to communicate. Ocular tracking devices track the user's eye movement and determine where on screen their gaze is targeted.
- Head control mouse, any type, describes an SGD accessory that monitors head movement and translates those movements into actions by the pointer on the SGD screen.
- Alternative input device, any type, describes any accessory other than an ocular tracking device or head control mouse, not integrated into the SGD hardware, used to control the actions of an SGD. Examples of alternative input devices include (not all-inclusive): specialty keyboards, joysticks, trackballs, trackpads, buddy buttons, jelly beans, beamers, roller balls, round pads, pal pads.

- Protective key guard, any type describes an overlay for a keyboard, alternative input device or SGD screen that assists the beneficiary in preventing inadvertent selection of a button, icon or other input.
- Electronic components that allow the SGD to be operated by the drive control interface of a power wheelchair.
- Mounting systems (HCPCS code E2512) are necessary to place SGD, switches and other access peripherals in a stable position relative to the user. Mounting systems may be used to attach to a wheelchair, desk or be a floor-based device.

Speech Evaluation

A speech evaluation is performed in order to determine the severity and motor deficit of each individual. This evaluation is conducted by a speech-language pathologist (SLP). The SLP is a licensed health professional, educated at the graduate level in the study of human communication, its development and its disorders. The SLP must hold a Certificate of Clinical Competence (CCC) in speech-language pathology from the American Speech-Language-Hearing Association. The SLP will be able to determine, based on the evaluation and on the natural course of the disease or condition, when a speech generating device or treatment is necessary and what type of device or treatment would best meet the needs of the specific patient in question.

Prior to the delivery of the SGD, the patient has had a formal evaluation of their cognitive and communication abilities by a SLP. The formal, written evaluation should 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 patient 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 patient of the upgrade compared to the initially provided SGD

Individuals with severe disabilities present a wide range of physical, cognitive, linguistic, sensory and motor deficits, as well as different daily communication needs. Upon completion of the evaluation, a speech generating device may be recommended according to the permanence and severity of expressive speech impairment, as well as the short- and long-term goals for these individuals.

Once the speech assessment of the individual has been completed, the following clinical indicators are used to evaluate the appropriate category of speech generating devices required to meet the individual's communication needs:

- The individual has a communication disability with a diagnosis of severe dysarthria, apraxia and/or aphasia.
- The individual's communication needs that arise in the course of current and projected daily activities cannot be met using natural communication methods.
- The individual requires a speech output communication device to meet his/her functional communication goals.
- The individual possesses the linguistic capability to formulate language (i.e., messages) independently.
- The individual will produce messages most effectively and efficiently using spelling.
- The individual will require a speech generating device with extensive language storage capacity and rate enhancement features.
- The individual will access the device most effectively and efficiently by means of physical contact, direct-selection technique, such as a finger, other body part, stylus, and hand-held pointer, head-stick or mouth-stick.

If the individual needs additional accessories to use the device, then the medical necessity of each accessory must be clearly documented within the evaluation. The use of only one speech generating device or speech generating program at a time is considered a medical necessity. This device or program should be limited to the primary language of the individual, not multilingual in capability.

Upgrades to these devices or programs must first be assessed through a speech-language evaluation. The SLP evaluation should clearly document the medical need for the upgrade.

Examples of Speech Generating Devices

Digitized speech devices that use prerecorded messages of less than or equal to eight minutes recording time, include, but are not limited to the following devices (i.e., HCPCS code E2500):

- BIGmack® (AbleNet, Inc., Roseville, MN)
- Cheap Talk 8 6-levels Communicator (Enabling Devices, Hawthorne, NY)
- GoTalk™ Series (Attainment Co., Verona, WI)
- Hip Talker (Enabling Devices, Hawthorne, NY)
- iTalk2™ Communication Aid (AbleNet, Inc., Roseville, MN)
- Little Mack® (AbleNet, Inc., Roseville, MN)
- One by Four Talker (Attainment Co., Verona, WI)
- Partner/One™, Partner/Two™ (Advanced Multimedia Devices, Inc. [AMDi], Farmingdale, NY)
- Personal Talker (Attainment Co., Verona, WI)
- Sequencer (Adaptivation, Sioux Falls, SD)
- Step-by-Step™ with Levels Communicator (AbleNet, Inc., Roseville, MN)
- Talking Brix™ Communicators (AbleNet, Inc., Roseville, MN)
- TalkTrac™ Plus or Plus with Levels (AbleNet, Inc., Roseville, MN)
- TECH/PLUS: 32 or 32+ (Advanced Multimedia Devices, Inc. [AMDi], Hicksville, NY)
- Tech/Speak (Advanced Multimedia Devices, Inc. [AMDi], Hicksville, NY)
- Tech/Talk (Advanced Multimedia Devices, Inc. [AMDi], Hicksville, NY)
- Ultimate 8 (Tash Inc., Richmond, VA)
- VoicePal, VoicePal Max or VoicePal Pro (Adaptivation, Sioux Falls, SD)

Digitized speech output devices that use prerecorded messages of nine to sixteen minutes include, but are not limited to the following devices (i.e., HCPCS code E2502):

- EasyTalk (Synapse Adaptive, San Rafael, CA)
- Hand Held Voice (Ability Research, Inc., Minnetonka, MN)
- MessageMate (Words+, Inc., Lancaster, CA)
- SuperTalker™ Progressive Communicator (AbleNet, Inc., Roseville, MN)

Digitized speech output devices that use prerecorded messages of 17+ minutes include, but are not limited to the following devices (e.g., HCPCS codes E2504 or E2506):

- DynaVox M3 (DynaVox Technologies, Pittsburgh, PA)
- EasyTalk (ET-24, ET-32) (ZYGO, Inc., Fremont, CA)
- Springboard Lite (Prentke Romich Company, Wooster, OH)
- Talara-32 (ZYGO Industries, Inc., Portland, OR)
- Tobii ATI s32 (TobiiATI, Dedham, MA)

Synthesized speech devices that require message formulation by spelling and access to physical contact with the device include, but are not limited to the following devices (i.e., HCPCS codes E2508, E2510):

- Allora (ZYGO Industries, Inc., Fremont, CA)
- E-talk Tablet (Synapse Adaptive, San Rafael, CA)

- DynaWrite™ 2.0 (DynaVox Technologies, Pittsburgh, PA)
- DynVox T10, DynaVox T15 (DynaVox Technologies, Pittsburgh, PA)
- Freedom 2000 (Words+, Inc., Lancaster, CA)
- Optimist MMX (ZYGO Industries, Inc., Fremont, CA)
- Nova Chat 8, Nova Chat 10 (Saltillo Corp., Millersburg, OH)
- Tobii Dynavox T7, Tobii Dynavox T10, Tobii Dynavox T15, Tobii I-12, Tobii I-15 (TobiiATI, Dedham, MA)
- Accent™ 800-M (Prentke Romich Company, Wooster, OH)
- Accent™ 1000-M (Prentke Romich Company, Wooster, OH)
- QuickTalker™ Freestyle (AbleNet, Inc., Roseville, MN)
- QuickTalker™ Freestyle mini (AbleNet, Inc., Roseville, MN)

Examples of speech generating software programs include, but are not limited to the following (i.e., HCPCS code E2511):

- Visual Suite (ProxTalker.com, LLC., Waterbury, CT)
- TapToTalk (Assistix LLC , Cupertino, CA)

U.S. Food and Drug Administration (FDA)

SGDs are classified as Class II devices by the U.S. Food and Drug Administration (FDA) and are exempt from the premarket notification procedures. The FDA has described these devices as: “system, communication, powered” devices”. The FDA identifies them as, “A powered communication system is an AC- or battery-powered device intended for medical purposes that is used to transmit or receive information. It is used by persons unable to use normal communication methods because of physical impairment.”

Use Outside of the US: No relevant information

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD	National	National Coverage Determination (NCD) for Speech Generating Devices (50.1)	7/29/2015
LCD	CGS Administrators Noridian Healthcare Solutions	Local Coverage Determination (LCD): Speech Generating Devices (SGD) (L33739)	1/1/2020

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

- Note:** 1) This list of codes may not be all-inclusive.
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Synthesized Speech Generating Devices

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
E2508	Speech generating device, synthesized speech, requiring message formulation by spelling and access by physical contact with the device
E2510	Speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access

Software Program

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
E2511	Speech generating software program, for personal computer or personal digital assistant

Accessories for Speech Generating Devices

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
E2512	Accessory for speech generating device, mounting system
E2599	Accessory for speech generating device, not otherwise classified

Pre-recorded Speech Generating Devices

Specifically excluded under many benefit plans:

HCPCS Codes	Description
E2500	Speech generating device, digitized speech, using pre-recorded messages, less than or equal to 8 minutes recording time
E2502	Speech generating device, digitized speech, using pre-recorded messages, greater than 8 minutes but less than or equal to 20 minutes recording time
E2504	Speech generating device, digitized speech, using pre-recorded messages, greater than 20 minutes but less than or equal to 40 minutes recording time
E2506	Speech generating device, digitized speech, using pre-recorded messages, greater than 40 minutes recording time

Not Medically Necessary

Considered not medically necessary when used to report multi-purpose, general consumer electronic devices:

HCPCS Codes	Description
E1399	Durable medical equipment, miscellaneous

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