



Speech Generating Devices Clinical Coverage Criteria

Overview

The American Speech-Language-Hearing Association (ASHA) defines augmentative and alternative communication (AAC) as an area of clinical practice that attempts to compensate (either temporarily or permanently) for the impairment and disability patterns of individuals with severe expressive communication disorders (i.e., the severe impairments in speech-language, reading and writing).

AAC is divided into two broad groups, known as unaided and aided forms of communication.

- Unaided forms of communication consist of nonverbal means of natural communication (including gestures and facial expressions) as well as manual signs and American Sign Language (ASL). These forms of communication can be employed by children and adults who are able to use their hands and have adequate fine-motor coordination skills to make fine-grained production distinctions between handshapes. Of course, communication partners must be able to understand the signs for communication to be functional.
- Aided forms of communication consist of those approaches that require some additional external support, such as a communication board with visual-graphic symbols that stand for or represent what an individual wants to express, or a speech generating device (SGD) that speaks for its user via either recorded (digitized) speech or synthesized (device-generated) speech.

A variety of Speech Generating Device (SGD) designs exist because individuals with severe communication disorders present a wide range of physical, cognitive, linguistic, sensory, and motor deficits, as well as different daily communication needs. As a practical matter, no single device can offer the number of features required to enable all individuals with AAC device needs to achieve effective and efficient communication. To address the varied needs of individuals with severe communication disabilities, SGDs are divided into three technologically and clinically distinct categories:

- SGDs with digitized speech output;
- SGDs with synthesized speech output, which require message formulation by spelling and device access by physical contact direct selection techniques; and
- SGDs with synthesized speech output, which permit multiple methods of message formulation and multiple methods of device access.

The key distinguishing features among the categories of SGDs are the type of speech output (which may be either digitized or synthesized) and, among synthesized speech output devices, the methods of message generation and device access. These design characteristics of SGDs make each category of devices unique technologically and clinically, in that each offers features that can be matched by use of distinct clinical indicators to individuals' profiles of physical, cognitive, linguistic, sensory and motor deficits, and to individuals' communication needs.

Definitions

Speech generating device (SGD) - An aided form of communication that provides a plan member who has a severe expressive communication disorder with the ability to meet his/her functional speaking needs. SGDs are characterized by:

- Being a dedicated SGD, or software that allows a laptop computer, desktop computer, tablet, or PDA to function as a speech generating device. Used solely by the plan member who has a severe expressive communication disorder, and
- May have digitized speech output, using pre-recorded messages, less than or equal to 8 minutes recording time, or
- May have digitized speech output, using pre-recorded messages, greater than 8 minutes recording time, or
- May have synthesized speech output, which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques, or
- May have synthesized speech output, which permits multiple methods of formulation and multiple methods of device access.

Digitized speech generating devices (E2500, E2502 - E2506) - Utilize words or phrases that have been recorded by an individual other than the SGD user for playback upon command of the SGD user. The amount of language that can be stored in a digitized speech AAC device varies greatly. The memory capacity ranges from a minute or two to an hour or more of speech. Although all AAC devices with digitized speech produce a finite number of pre-recorded messages (or message units), these messages can be changed to accommodate an individual's varying communication needs by simply recording new messages to replace those no longer needed.

Functional communication - The ability to express needs, wants, feelings, and preferences so that others can understand. Functional communication skills vary in their form and may include personalized movements, gestures, verbalizations, signs, pictures, words, and ACC devices.

Synthesized speech generating devices (E2508, E2510) - Translate a user's input into device-generated speech using algorithms representing linguistic rules. Users of synthesized speech generating devices are not limited to pre-recorded messages but rather can independently create messages as their communication needs dictate. Clinical indicators for these devices require that the individual have sufficient spelling skills to generate messages independently.

- E2508 devices require that the user make physical contact with a keyboard, touch screen or other display containing letters.
- E2510 devices permit the user multiple methods of message formulation and multiple methods of device access. Multiple methods of message formulation must include message selection by two or more of the following methods: letters, words, pictures or symbols. Multiple methods of access must include the capability to access the device by two or more of the following: direct physical contact with a keyboard or touch screen, indirect selection techniques with a specialized access device such as a joystick, head mouse, optical head pointer, light pointer, infrared pointer, scanning device, or Morse Code.

Speech generating software programs (E2511) - Software that enables a desk or laptop computer, a tablet, or personal digital assistant (PDA) to function as an SGD. Within this policy, the term SGD also describes these speech generating software programs.

Personal digital assistants (PDAs) - Handheld devices that integrate the functions of a small computer with features such as a cell phone, personal organizer, electronic mail or pager.

Mounting systems (E2512) - Devices necessary to place the SGD device, switches and other access devices within the reach of the patient.

Policy

This Policy applies to the following Fallon Health products:

- Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
- MassHealth ACO
- NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
- NaviCare SCO (MassHealth-only)
- PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Community Care (Commercial/Exchange)

Fallon Health requires prior authorization for speech generating devices.

Medicare Advantage

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for speech generating devices. Medicare has an NCD for Speech Generating Devices (50.1). NCD 50.1 states that the MACs acting within their respective jurisdictions have discretion to cover or not cover speech generating devices based on their individual reasonable and necessary determinations. Noridian Healthcare Solutions, LLC, the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) with jurisdiction in the Plan's service area has an LCD for Speech Generating Devices (L33739) (Medicare Coverage Database search 09/17/2024).

Coverage criteria for speech generating devices are fully established by Medicare, therefore the Plan's coverage criteria are not applicable. Refer to Noridian Healthcare Solutions, LLC, LCD for Speech Generating Devices (L33739) for coverage criteria.

Note: Desktop, laptop, tablet, smartphone and other hand-held computers (i.e. general computing devices) are not considered DME because they do not meet criteria Durable Medical Equipment benefit category requirements, even though they may serve a medical purpose. Medicare will reimburse for speech generating software only (HCPCS code E2511) when installed on a general computing device. The device itself must be coded A9270 (Noridian Healthcare Solutions, LLC, Speech Generating Devices (SGD) - Policy Article A52469).

[Link: NCD for Speech Generating Devices \(50.1\)](#)

[Link: LCD for Speech Generating Devices \(L33739\)](#)

NCD Speech Generating Devices 50.1

Version Number

2

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Item/Service Description

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.

Indications and Limitations of Coverage

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

A/B MACs acting within their respective jurisdictions have discretion to cover or not cover speech generating devices based on their individual reasonable and necessary determinations.

MassHealth ACO

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth has Guidelines for Medical Necessity Determination for Augmentative and Alternative Communication Devices and Speech Generation Devices, therefore, the Plan’s coverage criteria are not applicable.

[Link: Guidelines for Medical Necessity Determination for Augmentative and Alternative Communication Devices and Speech Generation Devices](#)

Important Note: When medical necessity for a SGD is established, such coverage may include both *dedicated devices* and—under certain circumstances set forth in state law, for individuals younger than 21 years of age with autism spectrum disorder—*non-dedicated devices*. The medical necessity for an SGD must be met regardless of whether the member's provider recommends a dedicated or nondedicated device.

NaviCare HMO SNP, NaviCare SCO

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

These Fallon Health Clinical Coverage Criteria apply to Community Care members.

Effective for dates of service on or after 10/15/2024, Fallon Health will use InterQual® Criteria when making medical necessity determinations for speech generating devices.

For coverage criteria, refer to the InterQual® Criteria in effect on the date of service:

- InterQual® CP:Durable Medical Equipment, Speech generating device, digitized speech, using pre-recorded messages, less than or equal to 8 minutes recording time (use for E2500)
- InterQual® CP:Durable Medical Equipment, Speech generating device, digitized speech, using pre-recorded messages, greater than 8 minutes but less than or equal to 20 minutes recording time (use for E2502)
- InterQual® CP:Durable Medical Equipment, Speech generating device, digitized speech, using pre-recorded messages, greater than 20 minutes but less than or equal to 40 minutes recording time (use for E2504)
- InterQual® CP:Durable Medical Equipment, Speech generating device, digitized speech, using pre-recorded messages, greater than 40 minutes recording time (use for E2506)
- InterQual® CP:Durable Medical Equipment, Speech generating device, synthesized speech, requiring message formulation by spelling and access by physical contact with the device (use for E2508)
- InterQual® CP:Durable Medical Equipment, Speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access (use for E2510)
- InterQual® CP:Durable Medical Equipment, Speech generating device, speech generating software program, for personal computer or personal digital assistant (use for E2511)
- InterQual® CP:Durable Medical Equipment, Speech generating device, accessory for speech generating device, mounting system (use for E2512)

- InterQual® CP: Durable Medical Equipment, Speech generating device, accessory or accessories for speech generating device, not otherwise classified (use for E2599)

Fallon Health makes InterQual criteria available to the public through the transparency tool on our website, effective January 1, 2024.

Additional Information:

Fallon Health will authorize a medically necessary SGD (defined herein) that is not more costly than an alternative that is at least as likely to produce equivalent therapeutic results for the treatment of the plan member's condition. Documentation must show that all least costly alternatives have been considered and ruled out before Fallon Health will authorize any SGD.

The Individuals with Disabilities Education Act (IDEA) specifies that special education services should enable students (ages 3 through 21) to access, participate in, and demonstrate progress with respect to the general education curriculum. It is hard to imagine a case in which a student would have equal access to the curriculum and the ability to participate and progress without benefit of an adequate means of spoken and/or written communication. Because assistive technology (AT) is one of the factors that individualized education plan (IEP) teams must consider for all children, IEP teams are obliged to discuss communication devices when a child's communication limitations are so severe that they impact the child's access to and potential benefit from the curriculum. The school district must provide the AT that is described in the IEP so that the IEP can be implemented in school. In addition, IDEA states that the use of school purchased AT devices in a child's home or in other settings is required if the child's IEP team determines that the child needs access to those devices in order to receive a free appropriate public education (34 CFR 300.105 (b)). This may include providing AT devices or software when needed for homework, or for functional skills that are necessary across environments, such as communication.

For all plan members 3 through 21 years of age, Fallon Health will require submission of the plan member's current IEP.

- When the IEP recommends an ACC device for use in school it is the responsibility of the school district to provide the device. Fallon Health will not provide coverage for an SGD when an SGD is recommended for use in school in the plan member's IEP.
- When the IEP does not recommend an SGD, the request for an SGD for plan members 3 through 21 years of age will be reviewed for medical necessity as described below.

Speech generating devices are covered under the Durable Medical Equipment benefit. A written prescription signed by the ordering provider is required.

It is the role of the speech-language pathologist (SLP) to conduct a thorough assessment and document the medical necessity of an SGD in a written evaluation. Written documentation includes all of the following information:

- Medical diagnosis, detailed physiological description of the underlying disorder with quantification of speech intelligibility, description of functional limitation, nature and severity of speech or communication impairment, and prognosis for improvement (or deterioration); and
- Medical justification for the SGD, and if a high technology communication device is requested, it is demonstrated that a low technology communication device is inadequate to meet the individual's functional communication needs; and
- Therapeutic history including speech, occupational, or physical therapies as appropriate; and
- Documentation of the cognitive ability to utilize the selected device; and
- Documentation of the visual, auditory, language and motor ability to utilize the selected device; and
- Documentation of the specific daily functional communication needs; and
- Expected functional communication goals with the device; and

- Plan of care for the use of the device: anticipated training needs, programming needs, evaluations, etc.

The SLP must recommend the least costly equally effective alternative, plus all necessary related items, such as software, a mount, or accessories.

If the individual is preliterate but it is anticipated that he or she will be able to learn to read and spell, the communication device selected should in addition have spelling and text capabilities.

The recommended SGD should be expected to be useful and functional for five years. Replacement or upgrading to new equipment would not be covered unless the plan member's physical ability to use their current equipment changes significantly. Repairs are covered after the manufacturer's warranty expires.

Exclusions

- Communication aids that do not generate speech (HCPCS code E1902) and related services (CPT codes 92605 and 92606). Examples include flashcards, story boards or talkers.
- SGDs for in school use when recommended in a plan member's IEP. This is the responsibility of the school system.
- Software that enables a laptop computer, desktop computer or PDA to function as an SGD is covered; however, charges for installation of the program and technical support are not covered.
- Internet service provider (ISP), phone service subscriptions or any modification to a patient's home to allow use of the speech generating device are non-covered because such services or modifications could be used for non-medical equipment such as standard phones or general computing devices.
- Altered auditory feedback devices for the treatment of stuttering.
- Voice amplifiers (designed to assist people who have problems with speech volume or intelligibility or who are experiencing vocal strain).
- Tracheoesophageal voice prostheses are not considered SGDs and are covered under the Durable Medical Equipment policy.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Fallon Medicare Plus, Fallon Medicare Plus Central, NaviCare and PACE plan members

Speech generating devices are covered under the Durable Medical Equipment benefit. To meet the DME benefit category requirements, the speech generating device must meet all of the following requirements:

1. Can withstand repeated use; and,
2. as an expected life of at least 3 years; and,
3. Is primarily and customarily used to serve a medical purpose; and,
4. Generally is not useful to an individual in the absence of an illness or injury; and,
5. Is appropriate for use in the home; and,
6. Be limited to use by a patient with a severe speech impairment; and,
7. Be primarily used for the purpose of generating speech, as defined above.

For criterion 7, a device utilizing tablet, smartphone or computer hardware must be designed by the manufacturer to function solely as a speech generation device, as defined above, at the time of initial issue.

Desktop, laptop, tablet, smartphone and other hand-held computers (i.e. general computing devices) are not considered DME because they do not meet criteria 3, 4, 6 and 7 above, even though they may serve a medical purpose. Medicare will reimburse for speech generating

software only (HCPCS code E2511) when installed on a general computing device. The device itself must be coded A9270.

The following features of a speech generating device are non-covered because they do not fall within the scope of the durable medical equipment benefit:

1. 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.
2. Video communications or conferencing.
3. Any computing hardware or software not necessary to allow for generation of speech, email, text or phone messages. Examples include, but are not limited to:
 - a. Hardware or software used to create documents and spreadsheets; or,
 - b. Hardware or software used to play games or music.

Internet service provider (ISP), phone service subscriptions or any modification to a patient's home to allow use of the speech generating device are non-covered because such services or modifications could be used for non-medical equipment such as standard phones or general computing devices.

A carrying case (including shoulder strap or carrying handle, any type) (E2599) is a convenience item and is denied as non-covered.

Accessories used with non-covered devices will be denied as non-covered.

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

MassHealth Guidelines for Speech Generating Devices

Per MassHealth Guidelines, when medical necessity for a SGD is established, such coverage may include both *dedicated devices* and—under certain circumstances set forth in state law, for individuals younger than 21 years of age with autism spectrum disorder—*non-dedicated devices*. MassHealth has designated HCPCS codes E2510 and E2511 to be used for billing for *non-dedicated devices*; hence HCPCS codes E2510 and E2511 are only covered for members who are less than 21 years of age with autism spectrum disorder.

Code	Description
E2351	Power wheelchair accessory, electronic interface to operate speech generation device using power wheelchair control interface
E2500	Speech generating device, digitized speech, using prerecorded messages, less than or equal to 8 minutes recording time
E2502	Speech generating device, digitized speech, using prerecorded messages, greater than 8 minutes but less than or equal to 20 minutes recording time
E2504	Speech generating device, digitized speech, using prerecorded messages, greater than 20 minutes but less than or equal to 40 minutes recording time
E2506	Speech generating device, digitized speech, using prerecorded messages, greater than 40 minutes recording time
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
E2511	Speech generating software program, for personal computer or personal digital assistant
E2512	Accessory for speech generating device, mounting system
E2513	Accessory for speech generating device, electromyographic sensor
E2599	Accessory for speech generating device, not otherwise classified

References

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Policy history

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language in Policy section, adopted InterQual® Criteria effective 10/15/2024).
UM Committee: 10/15/2024 (annual review).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.