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:

☒ Commercial

☒ Medicare Advantage

☒ MassHealth ACO

☒ NaviCare

☒ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National

Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare has an NCD for Speech Generating Devices (50.1). National Government Services, Inc. has an LCD for Speech Generating Devices (L33739) and an LCA for Speech Generating Devices. (MCD search 07-02-2021).

For plan members enrolled in NaviCare and PACE plans, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Each PACE plan member is assigned to an Interdisciplinary Team. When there is no Medicare or MassHealth guidance, the member's Interdisciplinary Team is responsible for coverage determinations.

Fallon Health requires prior authorization for speech generating devices (SGDs). These requests must be supported by the treating provider(s) medical records.

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.

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

Commercial plan members: Fallon Health considers an SGD medically necessary when all of the following medical necessity criteria are met:

1. The SGD has been recommended by a licensed speech language pathologist (SLP) who has conducted a thorough assessment. 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.; and

1. The individual has severe expressive speech impairment and alternative natural communication methods such as writing or sign language are not feasible or are inadequate for that individual's daily functional communication needs; and
2. The individual has completed a minimum one month trial of the device, has demonstrated the ability to use the device to produce functional communication.
3. If the individual has a degenerative disease causing the speech impairment, the communication device selected should be capable of modification to meet the individual's anticipated needs.

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.

Medicare members: Fallon Health follows Noridian Health Care Solutions LLC., Local Coverage Determination LCD (L33739) for Speech Generating Devices (L33739) and an LCA Speech Generating Devices (SGD) - Policy Article (A52469) for Medicare members including Medicare Advantage, NaviCare and PACE.

LCD link: **Speech Generating Devices (L33739)**
LCA link: **Speech Generating Devices (SGD) - Policy Article (A52469)**

Fallon Health will review requests for SGD's for Medicare members using the following criteria:

1. Prior to the delivery of the SGD, the beneficiary has had a formal evaluation of their cognitive and communication abilities by a speech-language pathologist (SLP). The formal, written evaluation must include, at a minimum, the following elements:
    - Current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of the impairment;
    - An assessment of whether the individual's daily communication needs could be met using other natural modes of communication;

- A description of the functional communication goals expected to be achieved and treatment options;
- Rationale for selection of a specific device and any accessories;
- Demonstration that the beneficiary possesses a treatment plan that includes a training schedule for the selected device;
- The cognitive and physical abilities to effectively use the selected device and any accessories to communicate;
- For a subsequent upgrade to a previously issued SGD, information regarding the functional benefit to the beneficiary of the upgrade compared to the initially provided SGD; and

2. The beneficiary's medical condition is one resulting in a severe expressive speech impairment; and
3. The beneficiary's speaking needs cannot be met using natural communication methods; and
4. Other forms of treatment have been considered and ruled out; and
5. The beneficiary's speech impairment will benefit from the device ordered; and
6. A copy of the SLP's written evaluation and recommendation have been forwarded to the beneficiary's treating physician prior to ordering the device; and
7. The SLP performing the beneficiary evaluation may not be an employee of or have a financial relationship with the supplier of the SGD.

If one or more of the SGD coverage criteria 1-7 is not met, the SGD will be denied as not reasonable and necessary.

Codes E2500 - E2511 perform the same essential function - speech generation. Therefore, requests for more than one SGD will be denied as not reasonable and necessary.

MassHealth members: Fallon Health follows coverage criteria in MassHealth Guidelines for Medical Necessity Determination for Augmentative and Alternative Communication Devices and Speech Generation Devices.

Guideline Link: **Augmentative and Alternative Communication Devices and Speech Generation Devices**

MassHealth bases its determination of medical necessity for AAC devices or software for devices that produce speech on clinical data including, but not limited to, indicators that would affect the relative risks and medical benefits related to the use of the equipment. These criteria include, but are not limited to, the following:

1. The member has a severe expressive communication impairment related to a medical condition or developmental disability that severely limits daily functional communication. AND
2. The member cannot meet daily functional communication needs by using unaided strategies. AND
3. The member has the cognitive, visual, language, and physical abilities to effectively use an AAC device. AND
4. A multidisciplinary team must recommend the device or software. The team must include a licensed, certified speech-language pathologist meeting nationally accepted knowledge and skill qualifications for augmentative and alternative communication service delivery. A licensed physician, nurse practitioner, or physician’s assistant must prescribe the device or software. Other professionals may be included as needed for determining motor or other needs, such as physical access to the device. AND
5. The recommended device, system, or software is the least costly, medically appropriate alternative. AND
6. For members under age 21, MassHealth covers non-dedicated devices under certain circumstances if the total net cost to MassHealth for the non-dedicated device is equal to or less than the total net cost of a comparable dedicated device.
   Specifically, MassHealth covers non-dedicated devices for:

- Members under 21;
- With a diagnosis of an autism spectrum disorder;
- Who meet MassHealth's prior authorization (PA) requirements set forth in these guidelines;
- Only if the total cost to MassHealth for a comparable non-covered, non-dedicated device is equal to or less than the net cost of the approved, covered (dedicated) AAC device. For purposes of this cost comparison, MassHealth will compare its net cost for a dedicated device after applying any costs covered by a member's insurance other than MassHealth (third party liability or TPL) to the cost of a non-dedicated device.

Note that all other MassHealth requirements apply and must be met, including but not limited to, member eligibility requirements and third party liability requirements, such as those related to MassHealth's role as payor of last resort. See e.g., 130 CMR 409.403 (member eligibility) and 409.428 (DME AAC provisions); 130 CMR 450.316 (TPL). MassHealth regulations at 130 CMR 450.105 specifically state, for each coverage type, which services are covered and which members are eligible to receive those services. AND

7. The recommended device or software matches the cognitive and physical capabilities of the member. AND
8. Device recommendations include the consideration of the impact of the presence of significant behaviors, if applicable, such as physical aggression and property destruction. AND
9. The member has demonstrated the ability to learn to effectively use the recommended device and accessories or software for functional communication as evidenced by a data-driven device trial supporting the ability to use the device and any necessary accessories functionally for communication.

For subsequent upgrade of a previously provided AAC device or software, the determination of medical necessity will also be based on additional clinical data including, but not limited to, clinical data-driven information that demonstrates why the initially covered AAC device or software is no longer clinically effective in meeting the member's medical need and that supports the functional medical benefit of the upgrade to the member in comparison to the initially provided AAC device or software.

<u>Noncoverage</u>

Under certain circumstances, MassHealth does not cover AAC devices or software for devices that produce speech. Examples of such circumstances include, but are not limited to, the following:

1. Devices or software used primarily for school or educational purposes.
2. Devices or software not limited to or configured to limit use to the purpose of communication (i.e., "dedicated" devices) except for non-dedicated devices that meet the state net cost comparison described in Section II.A.6. above for children under 21 years of age with autism spectrum disorder.
3. Multiuse and general use devices not configured to limit the primary use to a medical purpose, such as for use as a speech-generating device, and not configured to prevent uses unrelated to communication with the exception of medically necessary, cost effective, non-dedicated devices for children under 21 years of age with autism spectrum disorder as above.
4. Devices without accessories to protect them from damage.
5. Duplicate devices or software, including accessories for mounting and protection.
6. Web, cellular, or other device connectivity charges, and home modifications.
7. Failure to demonstrate during the trial period or at any subsequent time the ability to learn to use the device or software functionally for communication.).

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.
- 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.

Code	Description
92524	Behavioral and qualitative analysis of voice and resonance
92607	Evaluation for prescription for speech-generating-augmentative and alternative communication device, face-to-face with the patient; first hour
92608	Evaluation for prescription for speech-generating-augmentative and alternative communication device, face-to-face with the patient; each additional 30 minutes
92609	Therapeutic services for the use of speech-generating device, including programming and modification
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
E2599	Accessory for speech generating device, not otherwise classified

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Policy history

Origination date:	09/24/2003
Approval(s):	Technology Assessment Committee: 09/24/2003, 09/27/2011, 06/26/2012, 08/27/2014 (updated references and policy language) 01/27/2016 (added Medicare coverage rules, updated references), 03/22/2017 (added MassHealth Guidelines, updated references), 03/28/2018 (updated MassHealth guidelines, updated references), 02/27/2019 (updated references) *07/10/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section*

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.