



ATTACHMENT 1

PROPOSAL FOR REVISIONS TO NATIONAL COVERAGE DETERMINATION ON SPEECH GENERATING DEVICES

Proposed revisions to the NCD for SGDs (National Coverage Determination Manual (Pub. No. 100-03), § 50.1):

“Benefit Category

Durable Medical Equipment

Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Indications and Limitations of Coverage

Effective January 1, 2001, augmentative and alternative communication devices or communicators which are hereafter referred to as “speech generating devices” are now considered to fall within the durable medical equipment (DME) benefit category established by §1861(n) of the Social Security Act (the Act). They may be covered if the Medicare Administrative Contractor medical staff determines that the patient suffers from a severe speech impairment and that the medical condition warrants the use of a device based on the following definitions.

Definition of Speech Generating Devices

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 produces speech by translating the user’s input into device-generated speech;
- Being a ~~dedicated speech~~ device, 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; or

- 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, desktop 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 §1861(n) of the Act are characterized by:~~

- ~~Devices that are not 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 than non-medical function.~~

~~Laptop computers, desktop computers, or other marketed hardware PDA's which may be modified and programmed ~~to perform the same function as a~~ for speech generation.~~generating device, are noncovered since they are not~~ Such devices are covered speech generating devices and considered primarily medical in nature if the modification and programming otherwise meet the characteristics described above and are useful solely to the individual with a speech impairment. ~~and do not meet the definition of DME. For this reason, they cannot be considered speech-generating device 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.~~

Software that allows a laptop computer, desktop computer or personal digital assistant to function as a speech generating device meets the definition of a speech generating device.

Reasonable and necessary accessories for speech generating devices includes, without limitation, mounting accessories and access devices. For example, access devices such as but not limited to eye-tracking, switches, pointers, and scanners are used by patients with limited mobility to facilitate contact with the speech generating device.

Features and capabilities of the speech generating device that enable the individual to participate in activities other than speech generation do not render the device non-covered. Consistent with § 1834(a)(19) of the Social Security Act (42 U.S.C. § 1395m(a)(19)), the individual purchasing or renting the speech generating device has the right to choose an upgraded item, paying the supplier an amount equal to the difference of the applicable fee schedule amount for the standard item and the supplier's charge for the upgrade.



Rationale for Selection of Dedicated Speech-Generating Devices (SGDs) For Individuals With Complex Communication Needs October 2014

Augmentative and alternative communication (AAC) systems, including speech-generating devices (SGDs), provide a way for individuals with complex communication needs to communicate effectively and independently. SGDs are necessary when an individual cannot rely on natural speech to meet daily communication needs. The decision to use an SGD is made by a team comprising the individual, family members, and professionals, typically with the speech-language pathologist serving as the lead professional. SGD selection is determined by the patient's communication profile, functional abilities, and access needs.

Communication and Access Needs

The technology available for AAC users ranges from simple symbol communication boards, to off-the-shelf mobile technology with software applications, to customized SGDs. While mobile technologies with speech-generating software may be suitable to meet the needs of a limited number of AAC users, they are not broadly clinically applicable. Patients with complex communication and access needs that will progress or change overtime, such as those with amyotrophic lateral sclerosis (ALS), Parkinsonism, and other neurodegenerative diseases, largely require a traditional dedicated SGD. Considerations that support the speech-language pathologist's choice of a dedicated SGD as a primary communication tool include factors that are patient/environment related as well as factors that are device related.

When speech-language pathologists conduct a comprehensive AAC evaluation, the primary focus is communication effectiveness rather than the specific device or technology. In addition to speech and language evaluations, speech-language pathologists use a clinical decision-making process called "feature matching" to identify the capabilities of an individual with complex communication needs, followed by a comprehensive search for the clinically appropriate device and accessories that best match the patient's

strengths, abilities, and current and anticipated future needs. Other factors that influence device determination are the environments in which the SGD will be used and the primary communication partners. Combined, all of the factors result in a customized device specified for the individual's communication needs.

Advantages of Dedicated Speech-Generating Devices (SGDs)

For patients with complex motor, cognitive, language and literacy, and sensory-perceptual limitations, dedicated SGDs provide the following advantages over mobile technologies:

- Customizability and flexible programming options (e.g., auditory or visual selection features, language representation)
- Learnability
- Durability
- Compatibility with a variety of access and hardware needs, such as:
 - Switch interfaces or adapters
 - Switches, eyegaze trackers, keyguards, or pointers
 - Moisture guards or covers
 - Mounting devices/carrying systems for unique positioning needs
 - Lighting and touch modifications
 - Speaker systems for adequate volume in all environments
 - Enhanced screen size and capabilities
- Growth potential due to the dynamic ability to change over time to meet complex or future needs
- Higher quality speech output that can be synthesized or digital
- Device support for technical assistance, hands-on trials, training, repairs, and access to temporary loaners
- Availability of hardware/software upgrades, which enables long-term use of the same device, even with technology changes
- Extensive research and development for quality control

Research results reinforce the use of feature matching as part of the clinical decision-making process for SGDs for individuals with complex communication needs. A device-driven process has been demonstrated to result in a mismatch between the technology and the patient's communication goals or access needs. Successful communication

outcomes are the goal: positive effects on a patient's quality of life and independence in activities of daily living. For individuals with complex communication needs who require more sophisticated features to access SGDs, effective communication can be ensured by dedicated device availability.

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