

ASSISTIVE TECHNOLOGY LAW CENTER

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VIA ELECTRONIC DELIVERY: CAGinquiries@cms.hhs.gov
& Federal Express

Dr. Subash Duggirala
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
7500 Security Boulevard
Attention: CMS-1614-P
Baltimore, Maryland

RE: National Coverage Determination 50.1: Speech Generating Devices
MCD: Speech Generating Devices

Dear Dr. Duggirala:

I write as the Director of the Assistive Technology Law Center. I was designated by HCFA in 1999 as the requestor for the Formal Request for National Coverage Decision for Augmentative and Alternative Communication Devices (CAG 00055). The preparation of the *Formal Request* was specifically requested by Nancy Ann Min deParle, then the HCFA Administrator.

The *Formal Request* was prepared by a work group of the nation's leading clinicians, educators, researchers and advocates who are experts in the field of augmentative and alternative communication, which includes use of speech generating devices. This work-group subsequently called itself the Medicare Implementation Team. The comments that follow are submitted on its behalf.

Section 1: Executive Summary

Speech generating devices (SGDs) are a component of a long-standing and well-established speech-language pathology treatment methodology known as augmentative and alternative communication (AAC). Before 2001, the devices now known as SGDs were called "AAC devices." The Medicare SGD coverage guidance that became effective in 2001 was responsible for the name change.

SGDs are needed and used by, and provide essential benefits to individuals with severe or complex speech, language or communication impairments who are unable otherwise to meet their daily communication needs. SGD need is identified and a specific device and accessories (if needed) are recommended only after a comprehensive evaluation and report by a

speech-language pathologist. SGD need subsequently is confirmed by a written prescription from the beneficiary's physician. Since 2013, a face-to-face encounter between the Medicare beneficiary and physician also is required.

Medicare covers SGDs and related items such as SGD software, mounting systems and SGD accessories as items of durable medical equipment (DME). Their coverage is governed by a National Coverage Decision, a joint DMAC Local Coverage Decision and an interpretive clarification to the NCD. All of this coverage guidance became effective between January and May 2001. These guidelines also have served as a model for SGD coverage by numerous other health benefits programs.

In the 13 years since 2001, SGDs have been a very low incidence benefit: only approximately 2,000 Medicare beneficiaries per year obtained SGDs. There have been no reports of over-use or misuse of the SGD benefit.

On November 6, 2014, CMS opened an internal reconsideration of the NCD for SGDs. CMS stated this was appropriate and necessary because “[s]ince 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.”

As these comments make clear, whatever “changes” have occurred to SGD technology and their uses since 2001 are a matter of degree, not of kind. “Significant” changes to the NCD text are not required to address them. And, none of those changes creates conflicts with Medicare law, regulation or policy. There is no basis for CMS to change the scope of Medicare SGD coverage since 2001.

These comments identify the few and minor clarifications, updates and corrections to the NCD text necessary to achieve two outcomes: (1) as soon as possible, restore the scope of Medicare SGD coverage that existed since 2001; and (2) provide a clear and strong foundation in Medicare guidance for such coverage to continue into the future.

The following topics are addressed in the comments that follow. They explain that the NCD for SGDs should:

- Maintain coverage of off-the-shelf technology as SGD hardware;
- Maintain access to all capabilities and features that affect SGD function *as SGDs*;
- Maintain access to capabilities and features beyond speech generation that do not affect the primary and customary use of SGDs and are not useful to individuals without illness or injury, such as environmental control and phone control;
- Maintain coverage of eye tracking accessories for individuals with the most severe physical limitations in addition to severe speech, language or communication impairments;
- Update and correct SGD and related equipment items' HCPCS code descriptions

- Authorize, through DME upgrades and entirely at beneficiary expense, access to capabilities and features beyond speech generation that Medicare does not recognize as medically necessary; and
- Maintain the coverage option for Medicare beneficiaries of dedicated speech generating devices or of SGD software to be added to a beneficiary owned personal computer.

To achieve these outcomes, the following specific changes to the NCD text are appropriate and necessary:

[The proposed changes and additions to the existing National Coverage Decision for SGDs, are identified in red. Deletions to the existing text are ~~crossed-out~~]

National Coverage Decision for Speech Generating Devices

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 dedicated speech device, used solely by the individual who has a severe speech impairment;
- May be a dedicated personal computer or computer-based device and may be based on off-the-shelf hardware or purpose built hardware;
- May have capabilities and features such as wireless, Bluetooth connectivity, and others necessary for proper device operation and conveyance of full benefits as SGDs;
- May have capabilities beyond speech generation that do not affect the primary and customary use of the device as a speech generating device and are generally not useful to individuals without illness or injury, such as environmental control and phone control;
- May have digitized speech output, using prerecorded messages, less than or equal to 8 minutes recording time;
- May have digitized speech output, using pre-recorded messages, greater than 8 but less than or equal to 20 minutes recording time;
- May have digitized speech output, using pre-recorded messages, greater than 20 but less than or equal to 40 minutes recording time

- May have digitized speech output, using pre-recorded messages, greater than 40 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.

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 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 than non-medical function.
- ~~Laptop computers, desktop computers, or PDA's which may be programmed to perform the same function as a speech generating device, are nonecovered 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.

Speech Generating Software

Medicare coverage extends to ~~May be~~ software that allows a personal computer or computer-based device ~~laptop computer, desktop computer or personal digital assistant (PDA)~~ to function as a speech generating device.

Speech Generating Device Accessories

In addition to speech generating devices, Medicare coverage extends to mounting systems necessary to place the SGD, switches or other access devices within the reach of or otherwise appropriately positioned for the Medicare beneficiary. Medicare coverage also extends to accessories for speech generating devices that will provide access to Medicare beneficiaries with physical or sensory impairments in addition to severe speech impairment. Examples include: key-guards, optical head pointers, joysticks, switches, eye tracking accessories that will provide access to an SGD but will not control another device, and wheelchair integration devices.

Speech Generating Device Upgrades

Speech generating devices may be upgraded pursuant to § 1834 of the Social Security Act at Medicare beneficiary expense to provide access to capabilities or features that are not medically necessary, such as “unlocking” to provide access to non-speech communication methods, including internet and e-mail access.

Finally, because only a few clarifications, updates and corrections are appropriate and necessary to restore and protect Medicare SGD coverage, the reconsideration process should be completed as quickly as possible.

Section 2: Professionals Responsible for Preparation of These Comments

These comments were prepared by and are submitted on behalf of the *Medicare Implementation Team (MIT)*. The MIT is an informal work-group, initially created in 2001. Its members at that time were the SLPs, other professionals and advocates who wrote the *Formal Request for National Coverage Decision for Augmentative and Alternative Communication Devices* (1999) and who worked with Medicare staff to secure SGD coverage and to develop the Medicare SGD coverage guidance. Its initial mission and its present mission are the same: to provide information and resources to Medicare to ensure the requirements for and scope of Medicare SGD coverage are professionally sound, are consistent with current standards of professional practice, and will enable people with severe and complex communication impairments to obtain the most appropriate equipment to enable them to meet daily communication needs. Current members of the MIT include:

Meher Banajee, Ph.D., CCC-SP, New Orleans, LA
Lisa Bardach, M.S., CCC-SP, Ann Arbor, MI
Sarah Blackstone, Ph.D., CCC-SP, Monterey, CA
Kevin Caves, M.E., ATP, RET, Durham, NC
John Costello, M.A., CCC-SP, Boston, MA
Melanie Fried-Oken, Ph.D., CCC-SP, Portland, OR
Chris Gibbons, Ph.D., CCC-SP, Vancouver, WA
Amy Goldman, M.S., CCC-SP, Philadelphia, PA
Lewis Golinker, Esq., Ithaca, NY
Carolyn Higdon, Ph.D., CCC-SP, Oxford, MS
Richard Hurtig, Ph.D., Iowa City, IA
Joni Nygard, M.S., CCC-SP, Madison, WI
Patricia Ourand, M.A., CCC-SP, Baltimore, MD
Betts Peters, M.A., CCC-SP, Portland OR
Harvey Pressman, Co-Chair, Patient-Provider Communication Forum, Monterey, CA
Annette Stone, M.A., CCC-SP, Madison, WI
Shana Tognazzini, MS, CCC-SP, Portland, OR

Names in *Italics* =Members, Medicare Implementation Team, 2001.

Section 3: History of Medicare SGD Coverage

A complete review of the history of Medicare SGD coverage through the end of 2001 is posted for review at http://aacfundinghelp.com/funding_programs/medicare_history.html. As explained in that article, the period between June 1999 and May 2001 was critical to Medicare SGD coverage. In those 23 months, the Medicare coverage status of SGDs was totally

reversed: a National Coverage Decision expressly excluding SGDs from coverage was reconsidered, withdrawn and replaced by another National Coverage Decision and a subsequent interpretive clarification supporting SGD coverage almost without limitation. Additional Medicare guidance adopted a professionally sound SLP evaluation and reporting procedure to support SGD requests. Those developments were based on the data and other information provided in the *Formal Request for National Coverage Decision for Augmentative and Alternative Communication Devices* (1999). Also noteworthy is that all of the foregoing was accomplished through the efforts of the leading researchers, educators, clinicians and advocates in the field, none of whom had a financial interest in the outcome of the coverage policy review or guidance development process.

Of specific relevance to the present reconsideration of the 2001 SGD coverage guidance is that on many occasions during this period, Medicare staff exchanged information and met with the work-group that had written the *Formal Request*. This included hands-on equipment demonstrations; submission of product literature; and a tour of the Exhibit Hall at the 2000 Conference of the International Society for Augmentative and Alternative Communication, held that year in Washington, D.C., which offered the opportunity to see and speak with individuals using SGDs and SGD manufacturers. These interactions provided multiple opportunities for information about SGD hardware, and SGDs' non-speech generating capabilities, features and functions to be fully disclosed by observation, discussion and review of printed materials.

Among the non-speech generating capabilities of SGDs at that time were environmental control and phone control; and non-speech communication capabilities through e-mail and web-browsing.

For example, the product literature from 1998-2001 of Dynavox (now Tobii-Dynavox), Prentke Romich, Assistive Technology (now Tobii-Dynavox), and Words-Plus – then the largest SGD manufacturers – openly reported that some SGDs were based on off-the-shelf technology; offered touch-screens; had the potential for environmental control; could connect to a computer for preparation and editing of displays and back-up storage of device content; would support internet access, web-browsing and e-mail; and could connect to a telephone. Enkidu, then a new SGD manufacturer, used both off-the-shelf personal digital assistants (PDAs) as SGD hardware and not only used tablet computers as hardware for its SGDs, “Tablet” was the model name for the device.

As to environmental and phone control capabilities, Medicare staff noted that these were not the primary or customary use of an SGD and were generally not useful to individuals without illness or injury. Therefore, they were not relevant for coverage purposes.

As to the ability of some SGDs to offer e-mail and web-browsing, as well as access to other general computer functions, Medicare responded at first by excluding all computer- or PDA-based devices. But Medicare staff subsequently was informed that these devices could be made to function just as so-called ‘dedicated speech devices:’ all other capabilities, features and functions could be disabled. They then agreed that computer- and PDA-based devices that were modified to be “dedicated” were covered. *See* Letter to Lewis Golinker from Thomas Hoyer, Director Chronic Care Policy Group, Center for Health Plans and Providers, HCFA (May 4,

2001) attached as Exhibit 1. During those discussions, Medicare staff also were told the procedure that made SGDs dedicated was temporary and could be reversed, i.e., that the process of “locking out” these capabilities could be undone and the devices “unlocked.” They responded by stating that because SGDs were classified as “frequently purchased” DME, after the device was delivered it became the client’s property. And, Medicare policy allowed client-owned equipment to be modified in any way the client wished, at client expense. Medicare staff reported: ‘you can put headlights on a wheelchair if you want, as long as [Medicare] is not asked to pay for them.’

The foregoing is relevant because it provides the specific foundation for SLP and SGD manufacturer conduct and practice since 2001:

- SGDs with the opportunity for environmental and phone control were manufactured and distributed because Medicare staff recognized they create no conflict with any element of the Medicare DME definition and therefore are not relevant to coverage.
- Computer-based SGDs were recommended and distributed because the interpretive clarification to the NCD expressly stated they were covered, if made dedicated.
- SLPs’ client assessments focused on clients’ speech needs as required by Medicare, and also considered the totality of clients’ communication (including non-speech communication), safety and independent living needs, and they recommended “dedicated” computer-based SGDs that were able to be unlocked, and the SGD manufacturers offered a procedure for unlocking, because after SGD delivery the devices were then client owned and client owned equipment can be modified at client expense as the client wished.

That these characteristics of SGDs were consistent with Medicare coverage policy was reinforced further by decisions of the SADMERC and PDAC awarding coding verification to at least four dozen E 2510 SGD models between May 2001 and December 2013. A list of SGDs awarded coding verification between 2001 and 2013 is attached as Exhibit 2. These coding verification decisions are notable because almost all of these devices offered several non-speech generating capabilities, such as environmental and phone control and also had the ability to be unlocked to provide access to other non-speech communication capabilities such as e-mail, texting, and web-browsing. For example, among the first SGDs awarded coding verification after the 2001 NCD and other SGD coverage guidance went into effect were the PRC Pathfinder, Vanguard and Vantage. Coding verification for all three SGDs was issued on May 16, 2001. All three devices offered environmental control and computer control and the ability to store and back-up the device display to a computer or other storage device.

In addition, in the *Formal Request* and in subsequent communications with Medicare staff as part of the coding verification process with the SADMERC and PDAC, Medicare staff and others were informed of the existence and operational characteristics of, and the essential benefits provided by eye tracking SGD accessories. For at least one of the device listed in Exhibit 2 that was awarded coding verification: the My Tobii P-10, the SADMERC specifically reviewed an eye tracking module along with the SGD. Eye tracking coverage was further reinforced by an all but uniform sequence of claims approvals for these accessories since 2001 and the uniform reversal on appeal of the few claims that were denied.

There also were several audits of SGD manufacturers' Medicare claims which disclosed no over-use or misuse of the benefit. No person ever got a Medicare funding SGD who did not have a severe speech or language impairment. As to possible over-use, the opposite is true. From 2001 to 2013, Medicare purchased very few SGDs, consistent with the estimates in the *Formal Request*. The average number of devices Medicare purchased per year was about 2,000. The highest annual total was 3,000 devices. See Table 1.

Table 1: Medicare SGD Purchases: 2001 -2012

Year	SGD Codes							Total/Year
	K0541	K0542		K0543	K0544			
2001	66	93		119	476			754
2002	37	116		218	893			1264
2003*/			K0615	K0616	K0617			
2003	37	77	21	13	13	330	1128	1619
2004**/	E 2500		E2502	E2504	E2506	E2508	E2510	
2004	34		30	18	21	155	952	1210
2005	25		36	26	54	213	1547	1901
2006	16		34	22	79	195	1614	1962
2007	16		23	29	76	168	2041	2353
2008	18		33	33	75	130	2112	2401
2009	15		24	11	53	84	2349	2536
2010	9		11	2	47	61	2524	2654
2011	11		12	3	45	53	2597	2721
2012	47		8	3	28	52	2863	3002

Data Source: PDAC

*/ In 2003, Medicare revised the SGD codes for digitized speech output devices. One code was split into three. This change occurred after the year began. For this reason, data are reported for both the original code, K0542 as well as the three replacement codes: K0615, K0616, and K0617

**/ In 2004, Medicare changed the code labels, replacing the "K" codes with "E" codes.

Finally, in the period since 2001, Medicare coverage of SGDs has continued without substantive change. The few changes that did occur were minor, clerical and administrative in nature. For example, in 2003 as reported in Table 1, Medicare changed the HCPCS codes for SGDs by dividing one of the digitized speech output device codes into three, increasing the total number of SGD codes from four to six. In 2004, Medicare revised the HCPCS coding again, changing the code labels to "E" codes. Medicare also revised the "Regional Medical Review Policy" (2001) to be a Local Coverage Decision (LCD) and Local Coverage Article, but made no substantive changes to SGD coverage.

In sum, the practice of SLPs and other professionals to identify SGD need and of the SGD manufacturers to manufacture and supply devices, mounts and accessories to meet those needs for the entire period since 2001, has been tied specifically to:

- SGD capabilities, features and functions that existed prior to the development of the 2001 Medicare SGD coverage guidance and that were known to Medicare staff as the coverage guidance was written;
- Guidance provided by the 2001 Medicare NCD, LCD and interpretive clarification;
- Specific instructions given by Medicare staff;
- The consistent responses by Medicare decision makers regarding claims approval, coding verification and records audits; and
- The lack of any substantive change to Medicare coverage guidance.

Stated bluntly, since 2001 Medicare SGD assessment, documentation, and service delivery has been consistent with what Medicare staff and guidance documents intended and communicated to those responsible for the performance of these tasks. For these reasons, the Medicare announcement on November 6, 2014 that “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,” at most reflects changes of degree, not of kind. More importantly, however the changes are characterized, they provide no justification for “substantial” changes to the scope of SGD coverage or to the text of the NCD for SGDs. To the contrary, they support the restoration of the scope of SGD coverage that existed since 2001, and a few clarifications, corrections and updates to the NCD text to provide a more firm foundation for this scope of SGD coverage.

Section 4: MIT Comments Regarding Reconsideration of NCD for SGDs

The 2001 Medicare SGD coverage guidance: the NCD, LCD and interpretive clarification establish a scope of coverage that is sufficient to ensure Medicare beneficiaries with severe speech impairments can access SGDs to enable them to meet daily communication needs. In addition, this guidance provides an adequate foundation for SGD assessment, documentation and service delivery. For these reasons, the MIT recommends that the outcome of the present reconsideration process be a revised NCD for SGDs that maintains the scope of coverage and service delivery that existed since 2001. In addition, the MIT recommends that the revised NCD be issued as soon as possible to offset the harm that has been and is being done to Medicare beneficiaries with severe speech impairments. Stated below are the few clarifications, updates and corrections the MIT concludes are needed to provide a firm foundation in Medicare guidance for this scope of coverage to continue.

Comment # 1: Maintain Coverage of Off-the-Shelf Technology as SGD Hardware

Medicare has covered SGDs that rely on off-the-shelf technology, such as laptop or tablet computers since the May 2001 interpretive clarification to the 2001 NCD. The interpretive clarification was directed to the text of the 2001 NCD that stated dedicated speech devices were covered but computer-based devices were not covered. Specifically, the 2001 NCD stated:

Laptop computers, desktop computers, or 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.

However, Medicare staff subsequently agreed that the program's focus appropriately should be directed to device *function*, not SGD appearance or design. Neither SGD appearance nor design is a relevant factor related to Medicare coverage of an item of DME. Medicare staff also was persuaded that it should not be favoring one product design over another, particularly when they can be made functionally indistinguishable. This is particularly true for SGDs, the different models of which offer distinctions in features and function that enable clients with an extraordinary range of speech, physical and sensory impairments to meet daily communication needs. Medicare staff also was informed that as written, the 2001 NCD would have forced the manufacturers of computer-based SGDs to design new cases for their products, a process involving substantial expense and time – time during which SLPs would not be able to recommend those devices or the software that generates speech. Among the devices that would not be available were those manufactured by Words Plus, whose software was used widely by clients with ALS – clients who don't have the time to wait for their SGD to be put into a new "box." Also, in 2001 and for some devices today, SGDs based on off-the-shelf hardware are less costly than those that are 'purpose-built.'

After being told the foregoing and given a hands-on demonstration of prototypes of computer-based devices that had been modified to function in an identical fashion to so-called 'dedicated' devices, Medicare staff agreed to the May 2001 interpretive clarification of the NCD. As long as a computer-based device was modified to be "dedicated," and otherwise consistent with the NCD, it would be covered.

The manner in which notice of this agreement was to be distributed also was discussed. Initially, two proposals identified revisions to the NCD text, *i.e.*, that the second bulleted paragraph describing SGDs that are not covered (quoted above) be deleted, or that this entire section be re-written as an affirmative statement of the characteristics of SGDs that *are* covered. Ultimately, Medicare staff reported it would be administratively simpler and faster to implement if an interpretive clarification was stated in a letter which would be distributed to all Medicare decision makers and to other funding programs that are likely to rely on the Medicare SGD coverage guidance. This last option was selected and implemented.

The interpretive clarification caused no issues related to SGD coverage or service delivery until issuance of the "coverage reminder" in February 2014. Without explanation, it quoted the 2001 NCD text that computer-based SGDs were not covered.

Although the "coverage reminder" was withdrawn on November 6, 2014 it is appropriate for the present reconsideration to revise the NCD text to incorporate the interpretive clarification. To do so will meet the MIT's goal: for the NCD text to provide a firm foundation for the scope of SGD coverage since 2001 to continue. To accomplish this, and consistent with the MIT's recommendation that only a few changes to the NCD are required, its specific recommendation is that two revisions be made to the NDC text: (1) that the list of SGD characteristics add a specific reference to Medicare coverage for a dedicated personal computer and computer-based device and may be based on off-the-shelf hardware or purpose built hardware; and (2) that the NCD text delete the second bulleted paragraph (quoted above) describing the characteristics of devices that are not speech generating devices for Medicare coverage and payment purposes:

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:

* * *

- *May be a dedicated personal computer or computer-based device and may be based on off-the-shelf hardware or purpose built hardware;*

* * *

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 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 than non-medical function.*
- ~~*Laptop computers, desktop computers, or PDA's which may be programmed to perform the same function as a speech generating device, are noncovered 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.*

Comment # 2: Maintain Coverage of All Capabilities, Features and Functions that Support Device Function as an SGD

Medicare covered SGDs: “dedicated speech devices,” further defined as devices “used solely by individuals with severe speech impairment” require several capabilities, components, features and functions to operate effectively and efficiently *as SGDs*. The 2001 NCD did not restrict any of these operational characteristics of SGDs, including:

- Enabling the SGD manufacturers to connect wirelessly to devices to provide technical support, including troubleshooting device malfunction; and to make corrections to or upgrade software (independent of unlocking);
- Enabling devices to offer tutorials and provide other information that can be called up and reviewed on the device display;
- Enabling photographs to be installed onto the device display, either through transfer from another device, or through a built-in camera; and

- Enabling copying and storing of device content to protect against loss if the device malfunctions or was sent for repair.

Some of these device features are not within the client’s control (e.g., manufacturer connection to the SGD for technical support, troubleshooting, or software changes). None adds costs to Medicare. These features simply allow the device to function better as an SGD, and more effectively and efficiently meet clients’ daily communication needs.

No issue existed regarding these device features until issuance of the “coverage reminder” in February 2014. It referred specifically to “wireless” capability as disqualifying for Medicare coverage and payment and its text raised question about other similar features.

Although the “coverage reminder” was withdrawn on November 6, it is appropriate for the present reconsideration to revise the NCD text to address these features. To do so will meet the MIT’s goal: for the NCD text to provide a firm foundation for the scope of SGD coverage since 2001 to continue. To accomplish this, and consistent with the MIT’s recommendation that only a few changes to the NCD are required, its specific recommendation is that the revised NCD text state clearly and confirm that any capability, feature or function that enhances or supports device operation as an SGD will continue to be covered:

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:

* * *

- *May have capabilities and features such as wireless, Bluetooth connectivity, and others necessary for proper device operation and conveyance of full benefits as SGDs;*

Comment # 3: Continue to Allow SGD Manufacturers to Include Environmental Control Capability

Environmental control is the phrase used to describe the ability of SGDs to enable users to operate external systems that can control lights, appliances, door openers and locks, and home electronic devices, and access external alarm systems. The items subject to environmental control capabilities are collectively known as “electronic aids to daily living.” This SGD capability existed before the *Formal Request* was written, was known to Medicare staff as the 2001 NCD was developed, and it has continued to be included in SGDs to the present.

Environmental control is needed and used by persons with severe physical limitations to their fingers, hands or arms, in addition to their speech impairments. They use environmental controls as a functional substitute for their impaired physical abilities. Absent environmental controls, these tasks would have to be performed by a caregiver, either at home or in an institutional

setting. Environmental controls allow individuals with severe physical impairments to perform more tasks independently and improve their safety.

Environmental controls have 3 components: a transmitter of an electronic signal that will direct an action; a receiver for the signal; and an appliance, device or object that will respond to the signal. A common example: when a wall-plate is pressed, a transmitter sends a signal to a receiver that directs a motor to open or close the front door of an office building, hotel, or restaurant to allow entry or exit of a person using a wheelchair.

SGDs have long had the ability to serve as the signal transmitter for environmental control. This ability was a standard feature of devices, including purpose-built or dedicated devices. Including these features served an obvious purpose: people with SGD needs often have co-occurring physical impairments that require use of wheelchairs and make it impossible for the person to functionally use their fingers, hands and arms. An equally practical consideration was that incorporating this feature into the SGD eliminated the need for a second device to serve as signal transmitter – a device that would have to be placed and secured within the person’s reach and control, which often was very limited.

As only one component of an environmental control, the SGD did not “perform” any task by itself. To the contrary, substantial additional expense is required for the other two components: the signal receiver (also identified in SGD product catalogs as separate items that must be purchased at additional cost) and the appliances, devices and objects able to be controlled by this process. These expenses were entirely the client’s responsibility.

Medicare bore no additional costs as a result of this SGD capability. Environmental control was an SGD feature, provided with the device as delivered. It was not an SGD accessory or subject to additional charge. Thus, the issue related to environmental control as an SGD capability is one of *permission from* Medicare, not payment by Medicare.

When the 2001 NCD was being developed, Medicare staff knew of this capability, which was openly discussed in SGD product literature. They acknowledged that this capability would never be the “primary or customary” use of an SGD, instead of speech, and that environmental control capability is not generally useful to a person in the absence of illness or injury. Those with functional use of their fingers, hands or arms do not generally use an electronic tool to perform these tasks (e.g., family homes do not generally have electronic door openers). The significant costs required for the signal receiver and other equipment to modify doors and other items to operate by electronic control further reduces the “usefulness” of environmental controls in the absence of illness or injury. To the extent some appliances do offer remote control, this option is no more than a convenience or luxury option. For these reasons, Medicare staff offered no objection to environmental control as an SGD feature: its presence created no conflict with the Medicare DME definition and was not relevant to Medicare coverage.

While a convenience, luxury or extravagance for people without physical limitation, environmental control is of great importance to people with no functional use of their fingers, arms and hands. According to a 2014 survey conducted by the MIT, of 222 respondents who use

Medicare-funded SGDs, 51 % (113/222) reported that they used the environmental control feature of their SGDs.

Question: How often did Medicare recipients use their SGDs for environmental control?

Never	56	25%
Occasionally	9	4 %
Weekly	4	2%
Daily	68	31%
Hourly	32	14%
IDK or no response	53	24%

The importance of environmental control capability is most starkly demonstrated by the facts applicable to D--- S----, a woman in her late 30's who became a quadriplegic as a result of a car accident. Due to her injuries, Ms. S---- has limited use of her arms and no use of her hands. She also lost the ability to control her internal body temperature, making her prone to heat stroke and hypothermia. On one occasion, she had to be hospitalized due to heat stroke. She required an environmental control device to enable her to control the temperature and ventilation in her apartment. Also, despite her impairments, Ms. S---- lived in an apartment, independently and alone. Thus, an environmental control device also was needed to allow her to lock her doors and operate the telephone in an emergency. Before one could be obtained and installed, when a male acquaintance of Ms. S---- left her apartment following an argument, she was unable to lock the door. He later returned and re-entered her apartment, but she had no environmental control device to activate the telephone by voice and call for help. Even after she was raped, she was unable to obtain help until a care giver arrived, through the still unlocked door, hours later. *See S---- v. Comm'r, Minn. Dept. of Hum. Serv., 55-CO-95-2888 Order (Minn Dist.Ct. Olmsted Co. July 25, 1996).*

For individuals with complex communication needs and severe physical impairments, environmental control as an SGD feature is important to aid client safety and independence. A 2014 survey by the MIT of 40 respondents who used Medicare funded SGDs reported at least 35% (14/40) use their SGD environmental control functions to control an external call system to call for assistance, and at least 58% (23/40) used them to control the home environment, leading to increased independence in mobility and activities of daily living.

Question: If a Medicare recipient used environmental controls on his/her SGD, for what purpose did he/she use them?

Calling for assistance (by controlling an external call system; this does not include alert buttons within the SGD software)	14	35%
Controlling the home environment (e.g., opening doors, turning lights on or off, or controlling a heater or air conditioner)	23	58%

In general, environmental control will aid safety by

- Providing users the ability to access medical alerting systems to call for help;
- Allowing users to control access to the home, both to lock doors and to unlock them to allow access to the home to emergency responders (general advice to persons who have had a heart attack is to stay near a door to be able to unlock it for first responders).

They also promote independent living by:

- Enabling users to be left alone;
- Enabling independent access to care at home;
- Providing the ability to maintain family and parental roles; and
- Enabling the ability to pursue volunteer or community activities.

The extraordinary adverse impacts caused *just by* loss of effective speech due to acquired impairments such as ALS on individual's abilities to maintain their personal, familial, parental, and community roles is well established in the professional literature. *See e.g.*, Fox, L., and Sohlberg, Mck. "Meaningful Communication Roles," in Beukelman, D., Yorkston, K., and Reichle, J., Augmentative and Alternative Communication for Adults with Acquired Neurologic Disorders 3-24 (Baltimore: Brookes Publ. 2000). Those adverse effects can be mitigated substantially by provision of an SGD, but those abilities and benefits will be lost once again if individuals are left with no meaningful way to gain physical access to the sites where these roles and activities take place.

That SGDs included the ability to serve as a signal transmitter for environmental control was never an issue in regard to Medicare coverage and payment until issuance of the "coverage reminder" in February 2014. Without explanation, it referred specifically to "environmental control" capability as disqualifying for Medicare coverage and payment.

Although the "coverage reminder" was withdrawn on November 6, 2014 it is appropriate for the present reconsideration to revise the NCD text to address this SGD capability or feature. To do so will meet the MIT's goal: for the NCD text to provide a firm foundation for the scope of SGD coverage since 2001 to continue. To accomplish this, and consistent with the MIT's recommendation that only a few changes to the NCD are required, its specific recommendation is that the revised NCD text state clearly and confirm that Medicare coverage extends to SGDs with any capabilities beyond speech generation that do not affect the primary and customary use of the device as a speech generating device and are generally not useful to individuals without illness or injury, such as environmental control:

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:

* * *

- *May have capabilities beyond speech generation that do not affect the primary and customary use of the device as a speech generating device and are generally not useful to individuals without illness or injury, such as environmental control and phone control;*

Comment # 4: Continue to Allow SGD Manufacturers to Include Phone Connectivity and Phone Control Capability

A number of SGDs offer telephone *connectivity*, *i.e.*, they have had the ability to connect to telephones, either directly or through an intermediate device. This capability or feature allowed the SGD to send an electronic signal directly through the telephone network to a communication partner, who heard the message as speech. The SGD user would then be able to hear the communication partner's message by holding the handset or by use of a headset (both supporting private listening), or through a speakerphone. This ability pre-dated the *Formal Request*, was reported in SGD product literature, was known to Medicare staff as the 2001 NCD was developed, and continues to the present.

SGDs also offer an additional capability: telephone *control*, which operates in the same way as does the environmental control feature. The SGD display will include a facsimile of a telephone keypad and include cells for a phone's operating features: "placing," "answering," and "ending" a call. By making selections on the SGD display, the client is able to send a signal with instructions that will be executed by the telephone. This capability or feature is needed only by individuals with severe speech impairment and no functional use of their fingers, hands or arms. Their inability to use speech functionally makes it impossible for them to use their voice to control the phone. Their physical limitations make it impossible for them to hold or otherwise operate the phone. Thus, by sending an electronic signal to the phone, the SGD can serve as a functional substitute for their impaired physical abilities.

Like environmental control, both telephone connectivity and telephone control (hereafter *control*) are SGD features included with the device; they are not SGD accessories and do not involve any charge to Medicare (all costs of a phone capable of receiving and responding to electronic signals, a headset or a speakerphone are the client's responsibility).

Also like environmental control, this SGD capability or feature does not represent the primary or customary use of the device and serves no purpose whatever to a person without severe speech impairment who is able to speak directly into the telephone's microphone to send a message to a communication partner. Telephone control also creates no conflict with the Medicare DME definition and has no relevance to SGD coverage.

SGD telephone control capability or features are important because telephone use is as important for a person who must use an SGD to speak as it is for anyone. A 2005 survey of telephone use patterns by 24 SGD users reported that 57% placed and 42.1% received at least one telephone call on a daily basis. All respondents in this survey reported using the telephone at least once weekly. See Ball, L., Golinker, L., & Anderson, E., "Speech generating devices & telephone use," (2005) *NSLHA Networker*, June: 13-15.

The importance of SGD telephone control is stated most clearly by clients and caregivers:

- One young man indicated that his parents are divorced and he lives with his mother. His father lives across the state. He has relied on telephone control to communicate with his father. Without this option, he will not have a means to communicate with his parent.
- Source: <https://www.youtube.com/watch?v=U68DnGJMkPg&feature=youtu.be>. T---, a man with ALS in Portland, Oregon stated: “ALS robs you of all your voluntary muscle use. My future rides on my quality of life and how much suffering I can go through. The [SGD] is a life saver. I can communicate and text. Without it, I would just lay there and probably give up.”
Source: http://tdn.com/news/local/longview-man-with-als-a-better-communicator-thanks-to-new/article_88053942-6c68-11e4-a5c4-7fa60da14265.html.
- J---, wife and caregiver of B---, a man living with ALS in Portland, Oregon, stated to her SLP: “Having the ability for B--- to text message me makes all of the difference. It helps with normalcy, which is so important for a family. If I go to the store, he can message me to let me know what we need, or if something happens at home. This [the Medicare restriction on phone control] feels like we are being punished when we should be getting MORE help to overcome the limitations that we are already dealing with [as a result of ALS].” Source: personal statement.

In fact, telephone use may be of greater importance to individuals who need and use SGDs because they may have co-occurring physical or sensory limitations that make it difficult for them to travel. For these individuals, telephone access becomes a far more important means of maintaining contact with others, including family, health care providers, friends, religious institutions, community services providers, public safety offices, and stores. For example, telephone control enables the person who uses an SGD:

- immediate means to call (send information) for medical emergencies, personal safety, and in case of disaster;
- the ability to exchange information about health care issues with providers, manage communication about prescriptions, health care appointments and transportation to health care appointments; and
- to receive information about and respond to emergency alerts about disasters and emergency actions.

That SGDs included the ability to support telephone connectivity and to serve as a signal transmitter for telephone control was never an issue in regard to Medicare coverage and payment until issuance of the “coverage reminder” in February 2014. Without explanation, it referred specifically to “cellular communication” capability as disqualifying for Medicare coverage and payment.

The “coverage reminder’s” reference to “cellular communication” capability was mis-stated as well as mis-placed. SGDs do not typically have “cellular communication” capability, i.e., the

ability to function *as a telephone*. Instead, as described here, they serve as a means of telephone *access* and telephone *control* for people unable to otherwise do so due to physical disability.

Although the “coverage reminder” was withdrawn on November 6, 2014 it is appropriate for the present reconsideration to revise the NCD text to address this SGD capability or feature. To do so will meet the MIT’s goal: for the NCD text to provide a firm foundation for the scope of SGD coverage since 2001 to continue. To accomplish this, and consistent with the MIT’s recommendation that only a few changes to the NCD are required, its specific recommendation is that the revised NCD text state clearly and confirm that Medicare coverage extends to SGDs with any capabilities beyond speech generation that do not affect the primary and customary use of the device as a speech generating device and are generally not useful to individuals without illness or injury, such as telephone control:

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:

* * *

- *May have capabilities beyond speech generation that do not affect the primary and customary use of the device as a speech generating device and are generally not useful to individuals without illness or injury, such as environmental control and phone control;*

Comment # 5: Authorize SGD Manufacturers to Unlock SGDs: Allow DME Upgrades to Provide Access to Non-Speech Functions

For many years prior to development of the 2001 NCD some SGD models had been personal computer-based while others were ‘purpose-built.’ Of those that were computer-based, no modifications had been required or made voluntarily to limit access to their general computer functions. This included non-speech communication functions such as e-mail, and also other features such as web-browsing, and access to other computer programs. These capabilities were openly discussed in SGD product literature for these models. Nonetheless, computer-based devices were covered by other funding programs just as were other SGDs.

Only a few funding programs even took notice of these devices. Indiana Medicaid, for example, created a specific exception for computer based SGDs:

If authorization is requested for a computer or computerized device, the intended use of the computer or computerized device must be compensation for loss or impairment of communication function.

Likewise, Ohio Medicaid stated as an exception to an exclusion of personal computers:

Personal computers and related hardware [are not covered], unless components of a personal computer-based system that has been adapted for use as a communication device.

Others, such as Maine and New York Medicaid simply noted that the range of SGDs included computer-based devices. *See Formal Request*, at 57-58.

As the 2001 Medicare SGD coverage guidance was being developed, Medicare staff was aware of these devices and initially created the concept of “dedicated SGDs” as a way to ensure that SGDs met the Medicare DME definition. The first mention of dedicated SGDs in Medicare SGD coverage guidance is found in the draft RMRP for SGDs, issued October 24, 2000. It stated (and still states in the LCD Article):

Laptop computers, desktop computers, PDAs or other devices that are not dedicated SGDs are noncovered because they do not meet the definition of durable medical equipment.

Soon thereafter, in November 2000, the 2001 NCD was released in advance of its January 1, 2001 effective date. Its reference to “dedicated” SGDs was different. It stated that Medicare coverage was limited to

“dedicated speech device, used solely by the individual who has a severe speech impairment;”

And that

- Laptop computers, desktop computers, or PDA’s which may be programmed to perform the same function as a speech generating device, are noncovered 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.

Thus, as Medicare SGD coverage began in January 2001, computer-based SGDs were *not* covered at all. As explained in Comment # 1, above, this coverage restriction was quickly recognized as cosmetic rather than substantive: computer based SGDs could be modified to be functionally indistinguishable from “dedicated” speech devices. Access to their non-speech generating functions could be disabled or “locked.” Thus, as a matter of possible device *functionality*, the NCD’s rejection of the possibility that a computer-based SGD could be a ‘dedicated speech device’ was without foundation in fact as well as in law or policy. Once modified, the only difference between computer-based devices and those considered “dedicated” was their appearance or manner of assembly, neither of which was relevant to the elements of the Medicare DME definition.

The ability to modify computer based devices to function just as do dedicated SGDs was reported to Medicare staff in the Spring 2001. Written materials were provided, meetings were

held and hands-on demonstration of prototype “dedicated computer based devices” was conducted. Medicare staff were persuaded that these devices qualified for Medicare coverage and payment, and agreed to issue an “interpretive clarification” to the 2001 NCD. This was issued by letter dated May 4, 2001, and was distributed to all relevant Medicare decision and policy makers as well as individuals in comparable positions for Medicaid. *See* Exhibit 1.

As part of the discussion about Medicare coverage of dedicated computer based devices, Medicare staff were told that the process that disabled access to general computer functions and other programs, *i.e.* that resulted in these devices becoming “dedicated,” was temporary, and could be reversed. That the process of “locking” out functions and programs could be undone at a later time, and the devices could be “unlocked” allowing access to those functions and programs. Medicare staff stated no objection to this possibility because they noted that Medicare had classified SGDs as “frequently purchased” DME, and that after device delivery they became the client’s property. Medicare policy allowed client-owned equipment to be modified – at client expense – as the client wished. Medicare staff offered the following analogy: ‘if a beneficiary wants to put headlights on his wheelchair that is OK, as long as we [Medicare] are not expected to pay for it.’

Two comments are noteworthy about this communication. First, it was made to members of the MIT (an attorney and an SLP), and a representative of ASHA, who jointly led the presentation and demonstration of the dedicated computer-based SGD prototypes. None had any financial interest in the outcome of this presentation. Their interests were directed exclusively to ensuring Medicare beneficiaries had timely access to the most appropriate SGDs to meet their daily communication needs, and that those SGDs offered the full range of functionality that those individuals may find valuable. In addition, after the SGD manufacturers were told of the Medicare staff decision, they set the charge or fee for “unlocking” their dedicated computer-based devices as low as possible so that all Medicare beneficiaries who wanted access to these additional capabilities and features could take advantage of this opportunity. Ultimately, the fees for unlocking were set below \$ 100, in some cases substantially below that sum. Two points are being made here:

- although there were clear financial interests associated with Medicare coverage of dedicated-computer-based devices, *no one* had a financial interest in Medicare’s additional acceptance of the ability to unlock dedicated computer-based SGDs. Also,
- because the revenue generated by unlocking is so low in relation to the Medicare payment for SGDs, it is unreasonable in the extreme to conclude that SGD manufacturers would risk the latter by acting contrary to Medicare’s requirements to gain the former.

A third point about the capability of unlocking SGDs is that this opportunity resulted in no additional costs to Medicare. When elected, the charge for unlocking was paid entirely by the Medicare beneficiary.

Since May 2001, as a result of and in express reliance on the Medicare staff decision to issue the “interpretive clarification” to the 2001 NCD (Exhibit 1) and to not object to Medicare beneficiary requests – at their own expense – to unlock these devices after they became client

owned equipment, the SGD manufacturers offered dedicated computer based devices for Medicare purchase and a subsequent unlocking opportunity as beneficiary request.

That these devices and the unlocking opportunity were consistent with Medicare coverage policy was repeatedly reinforced between 2001 and 2013 by the award of coding verification for dedicated computer based devices with the capability of unlocking. At least four dozen devices were reviewed by the SADMERC and PDAC during this period and awarded coding verification. Almost all were computer based and could be unlocked. *See Exhibit 2, above.* As a matter of practice, not all SGDs were unlocked. For example, Lingraphicare America, also known as Lingraphica, has been the second largest supplier of SGDs to Medicare beneficiaries each year. It reported that approximately 2.5 percent of the devices it ships to Medicare beneficiaries are unlocked. Tobii-ATI reported that only about 21 percent of its SGDs were unlocked in 2011. The Prentke Romich Company reported that only about 9 percent of its devices were unlocked. Forbes Rehabilitation Services reported that only 12 percent of its SGDs were unlocked. These data support the conclusion that the majority of Medicare beneficiaries use their computer-based SGDs solely or exclusively for speech generation purposes, and that only a minority seek unlocking to access non-speech communication capabilities or other computer functions.

Unlocking appears to be diagnosis or condition-responsive. People with ALS and other speech and communication impairments that do not impair cognitive function appear to elect to unlock their devices more than individuals with other conditions. Research by Ball, Pattee and Beukelman, in press, is based on a medical records chart review for 64 individuals with ALS from 2001-2008. Results showed that 81 percent of their SGDs had been unlocked. The authors' conclusion was that

SGDs provide a vital link to communication for pALS. This group used multiple means of access and demonstrated a clear preference for unlocking features to enable access to common communication interfaces, such as Facebook, Twitter, and e-mail....

Ball, Pattee & Beukelman, AAC technology implementation patterns of individuals with Amyotrophic Lateral Sclerosis. Unpublished data (2014).

A March and April 2014 survey by the MIT of 119 respondents which also included many pALS among respondents reported a similar result. It found that 54% of Medicare funded SGDs had been unlocked. It also reported that the most common uses of or purposes for non-speech communication was to communicate about their needs and wants, to call for help, to get present needs met, to clarify needs with caregivers, and to give instructions to others.

In general, Medicare beneficiaries who opt to unlock their computer-based devices do so to maintain and support their independence and family and social roles. With access to e-mail, and web-browsing, for example, Medicare beneficiaries are able to use their SGDs to, *inter alia*:

- maintain and continue contact with family and friends who live far away or are otherwise unable to visit for face-to-face communication;

- participate in religious services and other community based activities they are unable to attend in person due to their inability to travel;
- call for help in an emergency using text-to-911 or instant message relay service assistance;
- send an instant message to a caregiver in another room to request assistance;
- access medical records, schedule appointments and communicate with health care providers via secure online healthcare portals such as MyChart;
- participate in telepractice visits with healthcare providers when travel to a clinic is impossible (including care that is not Medicare funded);
- using e-mail to communicate with paid caregivers about scheduling, clarification of tasks or other topics;
- access on-line user-guides, obtain technical support for training or other purposes related to their SGD;
- download page-sets for use with the SGD's communication software;
- participate in online support groups or patient communities such as PatientsLikeMe; and
- receive and respond to safety and emergency alerts sent by e-mail, or instant messages.

Objective data support these uses. For example, health communication interactions increasingly involve access to remote communication options like e-mail and texting. A recent study suggests that in the United States, almost 3 out of 10 physicians utilize e-mail messaging to communicate with patients. Sumathi, R. (2013) "When e-mail is part of the doctor's treatment" *The Wall Street Journal*, retrieved from <http://online.wsj.com/articles/SB1000142412788732437320045578376863506224702>; see also Singh, H., Fox, S. A., Petersen, N. J., Shethia, A., and Street, R. L. (2009). Older Patients' Enthusiasm to Use Electronic Mail to Communicate with Their Physicians: Cross-Sectional Survey. *Journal of Medical Internet Research*, 11, retrieved from <http://www.jmir.org/2009/2/e18/> (2009 Survey reported approximately half of respondents expressed enthusiasm about the possibility of using e-mail to communicate with their physicians); Brown, Julia. (2013). How to Master Electronic Communication with Patients. *Medical Economics*, retrieved from <http://medicaleconomics.modernmedicine.com/medical-economics/news/tags/health-insurance-portability-and-accountability-act/how-master-electroni?page=full> (reports of several surveys showing patients preferences for e-mail communication with physicians).

Medicare itself is a catalyst for the growth of electronic communication activities. To avoid Medicare payment penalties for unnecessary readmissions hospitals are assigning staff to conduct follow-up telephone calls to recently discharged patients to assure adherence to recommended protocols and medication procedures. Harrison, Patricia, Hara, Pamela, Pope, James, Young, Michelle, and Rula, Elizabeth. (2011). The Impact of Postdischarge Telephonic Follow-Up on Hospital Readmissions. *Population Health Management*, 14(1): 27–32. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3128446/>; Wall, Patrick. Nurses' Phone Calls to Patients Help Prevent Hospital Readmissions: Study. *DNAinfo*. Retrieved from

<http://www.dnainfo.com/newyork/20130717/norwood/nurses-phone-calls-patients-help-prevent-hospital-readmissions-study>; HRET. Implementation Guide to Reduce Avoidable Readmissions. U.S. Department of Health and Human Services. Retrieved from http://www.dcha.org/wp-content/uploads/readmission_changepackage_508.pdf; Jack, B.W., et al. (2011). A Reengineered Hospital Discharge Program to Decrease Rehospitalization: A Randomized Trial. *Ann Intern Med*, 150(3):178-87, retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/19189907>. To be successful, however, patients must have the ability to use these communication methods. That people who use SGDs are included among these patients is confirmed by a recent survey of 64 persons with ALS: 63 % (40/64) reported at least one hospitalization between 2001 and 2008. Ball, Pattee & Beukelman, AAC technology implementation patterns of individuals with Amyotrophic Lateral Sclerosis. Unpublished data (2014).

SGD users have stated the importance of these opportunities in their own words:

- D--- G----: “I understand that I am eligible for a new updated speech generating device, but that it wouldn't have internet access like my current device. I feel this is not right to take away from my already limited world. I do so much with my device; it is my access to the outside world.” Ms. G---- uses her unlocked SGD for a variety of purposes including participating in an online support group, communicating with friends and family via email and social media, shopping for clothing and other personal items, reading about medical research related to her condition, and keeping up on political news and current events. (Source: email communication)
- A--- F----: “[My current device] has the capability of being used to control the TV, email, go on the internet, be used as a phone, or even turn on the light switch. Medicare has decided that I cannot use these functions, and I am blocked from using them. This means that I cannot be left alone because I have no means of calling for help.”
(Source: https://www.youtube.com/watch?feature=player_detailpage&v=U68DnGJMKGp)
- Cy---: “Now email is the only way to keep in touch with far off family and friends. My world would have been very small without being able to unlock my device. ... I don't have a problem paying for additional features such as email, but the communication devices must have that possibility.”
(Source: <https://www.youtube.com/watch?v=BWDKQvk0dFc&feature=youtube>)
- C--- (caregiver of Cy---): “If it weren't for her email, nobody could really communicate with her on a one-on-one basis. It would always have to be third party. ... She blogs. If she couldn't blog, ... the communication between friends would be almost nonexistent. I challenge anyone [who is in a position to make decisions about SGD coverage] to go one week with nothing but [face-to-face communication].”
(Source: <https://www.youtube.com/watch?v=BWDKQvk0dFc&feature=youtube>)

- “I’ve spent the majority of my life trying to build interpersonal relationships through face-to-face communication. Now, however, the world is increasingly interconnected by the Internet. I use the Internet every day to do research, read news, check in with friends and family via various social networking sites, video chat once a week with a daughter at college and shop online for a myriad of products and services. I am able to do all these things because I have access to the tools and technologies I need to do them. It is vitally important these tools and technologies are available to all persons with complex communication needs.” M--- W----, 2011. Source Shane, Blackstone, Vanderheiden, Williams, M., & DeRuyter, F., (2012) “Using AAC technology to access the world,” *Assistive Technology*, 24.1:1-13.

Although the list of examples of how the non-speech generating capabilities of SGDs are used may appear long, in sum, they do not displace speech as the primary and customary use of SGDs. A 2014 survey by the MIT of 222 respondents who use Medicare funded SGDs reported that speech remains the primary use of their devices. Fried-Oken, M., & Peters, B. Survey of 222 Medicare recipients who use SGDs for communication functions. Unpublished data. (2014).

That computer-based SGDs included the ability to be unlocked at client request and client expense was never an issue in regard to Medicare coverage and payment until issuance of the “coverage reminder” in February 2014 and the change of the Medicare payment rule for SGDs from “frequently purchased” DME to “capped rental” DME. This change went into effect on April 1, 2014.

The “coverage reminder” stated specifically, but without explanation that SGDs that had the capability of “unlocking” were disqualified for Medicare coverage and payment. No condition or limitation was imposed on this prohibition, *i.e.*, that it would end when the device became client-owned equipment. Instead, it appeared to demand, without reference to authority, that the prohibition on unlocking be permanent; that it continue for the life of the device.

Although the “coverage reminder” was withdrawn on November 6, 2014 the payment rule change to “capped rental” creates another barrier to unlocking. As stated above, since May 2001 the basis in Medicare policy for unlocking was that the SGDs were client-owned equipment able to be modified at client expense as the client wishes. As of April 1, 2014 however, the date clients assume ownership changed from the date of device delivery to the end of the 13 month capped rental period. That delay will deny some Medicare beneficiaries with ALS the opportunity to ever access the non-speech communication and other computer functions: their lives may not extend that long after SGD delivery. The effect will be that the Medicare beneficiaries who most frequently seek these opportunities will not be able to access them. The individual effects on pALS will be devastating. That these adverse effects are tied to a change in a “payment rule” and not coverage policy makes them all the more unsupportable.

Because of capped rental, a new policy basis for unlocking at a time meaningful to Medicare beneficiaries is now required. That basis is DME upgrades, the authority for which is provided by statute. 42 U.S.C. § 1395m(a)(19). It will allow restoration of the timing of SGD unlocking as it existed since 2001. The statute expressly states upgrades apply to equipment that is rented

or purchased. “Unlocking” fits as the basis for SGD unlocking because SGDs are covered by Medicare as DME. Upgrades are defined as items that are desired by Medicare beneficiaries but which go beyond what Medicare considers medically necessary. Medicare guidance offers as examples deluxe models or deluxe features that exceed what Medicare will cover based on the beneficiary’s medical needs. The medical purpose of SGDs is recognized by Medicare to be “speech generation,” and access to non-speech communication and other computer functions are not recognized by Medicare as medically necessary. Upgrades are obtained at beneficiary request and at beneficiary cost. No additional cost to Medicare is incurred, just as none has been incurred since 2001 for SGD unlocking.

It is appropriate for the present reconsideration to revise the NCD text to address SGD unlocking through DME upgrade. To do so will meet the MIT’s goal: for the NCD text to provide a firm foundation for the scope of SGD coverage since 2001 to continue. To accomplish this, and consistent with the MIT’s recommendation that only a few changes to the NCD are required, its specific recommendation is that the revised NCD text state clearly and confirm that Medicare coverage extends to SGDs with the capability of unlocking and that unlocking is authorized by the Medicare’s DME upgrade authority:

Speech Generating Device Upgrades

Speech generating devices may be upgraded pursuant to § 1834 of the Social Security Act at Medicare beneficiary expense to provide access to capabilities or features that are not medically necessary, such as “unlocking” to provide access to non-speech communication methods, including internet and e-mail access.

Comment # 6: Maintain Coverage of Eye Tracking Accessories

The 2001 NCD does not refer to SGD accessories. Coverage for SGD accessories was first acknowledged in the RMRP for SGDs and by the establishment of HCPCS Codes K 0547 in 2001, subsequently re-classified as E 2599. As originally described in the 2001 RMRP, SGD accessories included:

Accessories for speech generating devices (E2599) include, but are not limited to, access devices that enable selection of letters, words or symbols via direct or indirect selection techniques. Examples of access devices include, but are not limited to, optical head pointers, joysticks, switches, wheelchair integration devices and SGD scanning devices. In addition, replacement accessories such as batteries, battery chargers and AC adapters are included in this code.

Eye tracking or eye gaze modules are one example of “access devices” that will enable persons with severe speech impairment and the most severe and restrictive physical impairments to continue to communicate. The conditions most commonly associated with eye tracking need, use and benefit are ALS, cerebral palsy, Rett Syndrome, brain stem stroke, and traumatic brain injury. These conditions or their progression leave some people with no voluntary muscle control, except for eye movement. Eye tracking modules extend the reach of SLP treatment by providing a means for these persons to continue to communicate. Their availability pushes back

the point where the response must be ‘there is nothing else we can do,’ which always has been one of the core goals and purposes of AAC interventions.

Eye tracking modules operate by monitoring where a person’s eyes are focused in relation to the SGD display. By maintaining focus on a particular word, phrase, message or image on the display, the module recognizes that a selection is being made. This process is repeated until a message is complete, and the SGD will then be directed to produce the message as speech. They are natural and fast, not physically demanding, and do not require anything to be attached to the person’s body to make it work. Ball, L., Nordness, A., Fager, S., Kersch, K., Pattee, G., & Beukelman, D. (2010). Eye gaze access of AAC technology for persons with amyotrophic lateral sclerosis. *Journal of Medical Speech Language Pathology*, 18, 11-23. Eye tracking modules fall within the sub-set of SGD accessories known as *electronic aids to direct selection*. Viewed most generically, an eye tracking module can be analogized to a computer mouse that is moved around the device display and operated by eye movement.

Eye tracking modules initially were developed in the late 1980s, long before the 2001 NCD was developed. MIT members and Medicare staff discussed them in July 1999 when development of the *Formal Request* was first discussed. Eye tracking modules are referenced in the *Formal Request* as an SGD accessory, see Table 14 at 82. After the 2001 Medicare SGD coverage guidance went into effect, the first known approval of an eye tracking module approval was in March 2002. Since then, until the Fall 2013, eye tracking modules were uniformly approved by all Medicare contractors; the few claims that were denied were uniformly approved in subsequent appeals, up to and including the Spring 2014.

Medicare coverage and approval of claims for eye tracking modules should be a matter of routine. Their coverage is based on HCFA Ruling 96-1 (Sept. 1996) and Medicare Benefit Policy Manual, Ch. 15, § 110.3. The HCFA Ruling states:

Accessories used in conjunction with, and necessary for the full functioning of, durable medical equipment fall under the durable medical equipment benefits category.

HCFAR 96-1 at 1.

It subsequently adds:

To the extent that [equipment items] that ... may or may not function properly or not achieve its full “therapeutic benefit” without attached components ..., the attachments are appropriately viewed as a necessary accessory that is an integral part of the durable medical equipment and is, accordingly payable as durable medical equipment provided that the other prerequisites for classification as durable medical equipment are met.

HCFAR 96-1 at 4-5.

The Medicare Benefits Policy Manual at Ch. 15, § 110.3 confirms this standard for DME accessories coverage, stating that items “Payment may be made for [items] necessary for the

effective use of durable medical equipment. Such [items] include [those necessary] ... to assure the proper functioning of the equipment....”

SGD eye tracking modules easily satisfy all of these requirements:

- To operate, they must be “attached components” to an SGD.
- They are then used “in conjunction with” the SGD.
- Their use is *essential* not just “necessary” for the full functioning of the SGD.
- For individuals able to effectively and efficiently control only the movement of their eyes, an SGD will not “function properly:” it will not function *at all* without an eye tracking module.
- For individuals who require an eye tracking module, the outcomes of its use or non-use are binary. Absent their availability, the person will have no means whatever to direct the SGD to formulate messages or to direct the device to produce them as speech. The SGD will be able to provide *no* “therapeutic benefit,” the polar opposite of its potential to provide “full therapeutic benefit.”
- For individuals who require an eye tracking module, access to this access aid is required for there to be *any use whatever*, not just “effective use” and *any functioning whatever*, not just “proper functioning” of the SGD.

Finally, eye tracking modules meet all of the “other prerequisites for classification as durable medical equipment.”

The Medicare definition of durable medical equipment states that equipment must have the following characteristics:

Durable medical equipment means equipment, furnished by a supplier or a home health agency that—

- (1) Can withstand repeated use;
- (2) Is primarily and customarily used to serve a medical purpose;
- (3) Generally is not useful to an individual in the absence of an illness or injury; and
- (4) Is appropriate for use in the home. (See § 410.38 of this chapter for a description of when an institution qualifies as a home.)

42 C.F.R. § 414.202.

There is no question that an SGD eye tracking accessory is able to withstand repeated use. These modules were designed for repeated, daily use for an extended period, measured in years. For a person with ALS in particular, they are expected to be of use for the life of the recipient. Items not able to satisfy this criterion are consumable or disposable, intended to be used once and thrown away. An eye tracking module has none of these characteristics. Likewise, an SGD eye tracking accessory is appropriate for use in the home. SGDs generally are appropriate for use in the home or wherever the need to communicate will arise. An SGD eye tracking accessory will provide access to enable a person to access and control that SGD in the home and all other

environments. Moreover, as a practical matter, based on the level of physical impairment required to give rise to medical need for an eye tracking module, the primary if not sole location of use will be the person's home. Their physical impairments will make most out of home activity or travel difficult to impossible.

The DME definition also requires equipment items to be "primarily and customarily used to serve a medical purpose." SGDs are covered by Medicare as items of DME, and the medical purpose recognized for SGDs is "speech." All an eye tracking module will do is enable a person to access and control, and thereby derive benefit from an SGD. In this regard, an eye tracking accessory cannot be distinguished from the SGD battery. The battery enables the device to work, to be used, to provide benefit. The eye tracking module serves the same purpose. It has no independent or other function.

Moreover, the 2001 NCD states that speech generating devices eligible for Medicare coverage and payment must be "dedicated speech devices," "used solely by the individual who has a severe speech impairment." Again, the only role of the eye tracking module is to overcome the physical limitations that will otherwise prevent an individual from using, controlling, and deriving benefit from a Medicare compliant SGD. As previously explained in regard to HCFAR 96-1, for Medicare beneficiaries who have no other effective means of access, an SGD will provide no therapeutic benefit without this accessory.

SGD eye tracking accessories also are "generally not useful to an individual in the absence of an illness or injury." This is an obvious point: a person without a severe speech impairment will not consider, be evaluated for, recommended for, prescribed, seek, incur a co-payment for, use or benefit from *an SGD*. Instead, the person will just speak aloud what he or she wishes to communicate. Equally true, a person with a severe speech impairment who needs an SGD but who has no physical or sensory impairments will use his or her fingers to formulate messages. There will be no consideration of, evaluation, recommendation or prescription, funding request or co-payment for, use of or benefit from *any SGD access aid*.

Other individuals with impaired physical abilities will use the most appropriate access aid that will enable them to most effectively and efficiently use and benefit from the SGD and thereby meet daily communication needs. As noted in the Medicare SGD coverage guidance quoted above, there are is a wide range of SGD access aids, responding to the many different ways in which physical and sensory limitations are manifested. Even among these persons, *all of whom have an illness or injury*, only those with the most severe and limiting physical impairments, for whom there is no other effective alternative means of access – no other means of communicating – will consider, seek, use and benefit from an SGD eye tracking accessory.

As a final point, SGD eye tracking accessories are not able to control devices other than SGDs. They are not "transferable" or "interchangeable." The SGD manufacturers achieve this result in several different ways:

- Tobii-ATI hard-wires its eye tracking modules into the other components of its SGDs, which are within the device case. There is no way for a Medicare beneficiary to access the connection, or remove it for installation in or use with another device. In addition,

the eye tracking module installed in Tobii's SDGs is unique: it is not used on any other Tobii-ATI product.

- Dynavox's eye tracking modules relied on male-female connectors between the module and the SGD that were unique: they are not common to ordinary personal computers. Thus, there is no way to connect one of these modules to another device.
- The Prentke Romich Company purchases its eye tracking modules from a third-party supplier. It has an exclusive contract with that supplier such that it is only available for use with PRC SDGs.
- Eye tracking modules require software to control its eye monitoring function, to calibrate the point on the SGD display being viewed and controls the selection function, and to link with the SGD software to enable messages to be formulated. This software for the eye tracking modules used with PRC and LC Technologies' SDGs is installed in the SGD, and is not available to the Medicare beneficiary for transfer to, installation in, and use with another device. Thus, even though the eye tracking modules used by both companies rely on standard USB-type connectors, and therefore, can be plugged into some types of personal computers, without the software, the modules will not function: they will not work.

Through these techniques: physically installing the module within the SGD case; using unique connectors; having exclusive distribution agreements; and restricting access to operating software, SGD eye tracking modules cannot control another device. Their purpose is exclusively to provide access to SDGs; SDGs are needed and used by and provide benefits only to people with severe speech impairment who are unable otherwise to meet daily communication needs.

That SGD eye tracking modules meet the Medicare DME definition and all the other criteria for coverage as an SGD accessory is further confirmed by the repeated award of coding verification for these items by the SADMERC and PDAC. At least eight SGD eye tracking modules have been awarded coding verification:

- Tobii-ATI obtained code verification for its P-10 SGD, the first SGD to have an eye tracking module physically installed within the SGD case, in 2006. A later model eye tracking module was awarded coding verification in July 2011.
- LC Technologies obtained coding verification for two eye tracking modules: the first in 2007, and the second in 2009.
- PRC obtained coding verification for two eye tracking modules in 2011 and 2012. And
- Forbes Rehabilitation Services obtained coding verification for two eye tracking modules in 2012 and most recently, in 2014.

Medicare claims payment practices further confirm the conclusion that SGD eye tracking modules meet all the requirements for Medicare coverage and payment. Since 2002 when the first known eye tracking claim was approved, SGD eye tracking modules have been uniformly approved by all Medicare DMERCs and DMACs. The few claims that were denied, were uniformly approved in subsequent appeals.

Medicare coverage and payment for SGD eye tracking accessories continued without concern or issue until the Fall 2013. At that time, claims for these accessories began to be denied. This occurred absent any relevant change to

- the Medicare statute;
- the regulation defining DME;
- the relevant Medicare policy regarding DME accessories coverage;
- the coverage status as DME of SGDs;
- the coverage status of SGD accessories, generally; or
- the nature or characteristics of the eye tracking modules.

Only the outcome of SGD eye tracking accessories' claims changed: from covered to non-covered, without further explanation or reference to authority.

The present effects of these denials has been muted because the SGD manufacturers continue to accept assignment for SGD eye tracking modules and are pursuing appeals. However, the appeal process is overloaded and delays of up to 24-36 months are possible. The ability of the SGD manufacturers to continue to provide these accessories with only a chance of payment two to three years in the future is as uncertain as it is unnecessary.

For the past year, Medicare beneficiaries who need an SGD with an eye tracking modules have been under siege. The consistent message from Medicare has been that they are not covered; the ongoing voluntary practice of the SGD manufacturers to accept assignment for these accessories can end at any time. This uncertainty has been imposed primarily on people with ALS, for whom eye tracking modules serve as their only communication link to other people.

The importance of eye tracking modules to these Medicare beneficiaries is best shown by their own words:

- M--- K----: "My wife's last words were spoken on the ALS eye gazer (SGD accessible via eye tracking) 2 hours before she passed. "Love you all". Thank you from the bottom of our hearts." [This patient had ALS and was unable to use any part of her body other than her eyes. She had an SGD with eye tracking provided on loan from ALS of Michigan. Source: Personal communication via letter and phone.]
- J--- W----: "I hope my wife continues to be well enough to use the Tobii. Her condition is dire. Our son turns 8 tomorrow. She is composing a little birthday message for him. It will be the first thing she's been able to tell him in a while. There's no way to thank you enough for getting this device to us." [This patient with ALS and Lupus used an SGD with eye tracking after she was no longer able to use a head mouse for access. While she was alive, she wrote notes every day to her 8 year-old son. Her husband printed them out and her son saved every one. Source: personal communication via email]
- L--- M----'s sister reported that Lynda is now able to communicate much more effectively and participate in conversations, family gatherings, medical appointments, and many other environments because eye gaze access is so much less fatiguing than single switch

scanning. She further reported that her sister is now able to say exactly what she wants at length and no longer requires assistance or interpretation because of fatigue. [Source: personal communication.]

- N--- G---- reported in an e-mail: “If I didn’t have text capability to get help I would have to pay someone to stay with me all day or my girlfriend would have to quit her job. I use e-mail to communicate with doctor and family. If I did not have this I would have to ask caregivers to help and they are doing everything else for me. I would hate to ask them to do more. My doctor and the hospital use [an] online system to make or change appointments. This works good [sic] for me since I cannot talk. I also use the internet to do banking and pay bills. ... I could not use my SGD without the eye gaze. ...” [Source: personal communication.]
- D--- J---- reported in an e-mail: “I am using a headmouse now but my neck muscles are weakening. We have just started on the journey to get eye gaze. If I am not able to get this added to my SGD I will be rendered mute and isolated, completely unable to communicate except by blinking my eyes.”
- V--- T---- was described as “isolated in a public housing unit in the North Side of Pittsburgh and paralyzed by ALS, [he] hears about school from his two preteen kids by texting with them from his device. With his eyes, he selects each letter [to write] notes delivered to his children, who live with their mothers.” [Source: [http://publicsource.org/investigations/silent-community-speaks-out-about-communications-technology#.VIDNHwD0zIU.](http://publicsource.org/investigations/silent-community-speaks-out-about-communications-technology#.VIDNHwD0zIU)]

Medicare’s position for the past year that SGD eye tracking accessories are different from other access aids needed by people with physical limitations is without foundation in history, fact, policy, or practice. It causes the denial of equal access – literally as well as legally – to the Medicare DME benefit, by denying people with the most severe disabilities access to effective treatment through use of an SGD. Eye tracking modules are used only by people with significant physical disabilities who are unable to use other access methods. These modules cannot control devices other than an SGD. Denying coverage of these accessories leaves these individuals unable to communicate.

The current reconsideration process for the 2001 NCD gives Medicare the opportunity to update the omission of SGD accessories as covered items from the NCD and in particular gives Medicare the opportunity to confirm in its SGD coverage guidance that SGD eye tracking accessories that will not be able to control other devices, are covered DME and SGD accessories. To do so will meet the MIT’s goal: for the NCD text to provide a firm foundation for the scope of SGD coverage (including accessories) since 2001 to continue. To accomplish this, and consistent with the MIT’s recommendation that only a few changes to the NCD are required, its specific recommendation is that the NCD text be revised as follows:

Speech Generating Device Accessories

In addition to speech generating devices, Medicare coverage extends to mounting systems necessary to place the SGD, switches or other access devices within the reach of or otherwise appropriately positioned for the Medicare beneficiary. Medicare coverage also extends to accessories for speech generating devices that will provide access to Medicare beneficiaries with physical or sensory impairments in addition to severe speech impairment. Examples include: key-guards, optical head pointers, joysticks, switches, eye tracking accessories that will provide access to an SGD but will not control another device, and wheelchair integration devices.

Comment # 7: Update and Correct the SGD and HCPCS Codes

The 2001 NCD describes the SGD “codes” used by Medicare (and other funding programs) for payment purposes. It states:

Speech generating devices are characterized by:

- digitized speech output, using prerecorded messages, less than or equal to 8 minutes recording time;
- digitized speech output, using prerecorded messages, greater than 8 minutes recording time;
- synthesized speech output which requires message formulation by spelling and device access by physical contact with the device-direct selection technique;
- synthesized speech output which permits multiple methods of message formulation and multiple methods of device access; or
- software that allows a laptop computer, desktop computer, or personal digital assistant (PDA) to function as a speech generating device.

These code descriptions are both incomplete and incorrect. They are incomplete because no mention is made of the codes for SGD mounts or SGD accessories. They are incorrect because one of the digitized speech output device codes was split into three. Instead of four device codes, there are now six. In total, there are nine codes for SGDs, software, mounts and accessories.

In addition, the text of the 2001 NCD refers to desktop computers, laptop computers and personal digital assistants (PDAs). These terms no longer accurately reflect the technology.

The reconsideration process gives Medicare the opportunity to update and correct the code descriptions, to insert the omitted code descriptions for SGD mounts and SGD accessories, and to update the vocabulary that describes the equipment used as SGDs. As to the SGD accessories code description, Medicare also should state clearly and confirm that eye tracking accessories are among covered SGD accessories.

The MIT recommends that the NCD text be revised as follows to address the scope of SGD coverage:

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:

- *
- *
- *
- *May have digitized speech output, using prerecorded messages, less than or equal to 8 minutes recording time;*
- *May have digitized speech output, using pre-recorded messages, greater than 8 but less than or equal to 20 minutes recording time;*
- *May have digitized speech output, using pre-recorded messages, greater than 20 but less than or equal to 40 minutes recording time;*
- *May have digitized speech output, using pre-recorded messages, greater than 40 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;*

...

Speech Generating Software

Medicare coverage extends to software that allows a personal computer or computer-based device, to function as a speech generating device.

Speech Generating Device Accessories

In addition to speech generating devices, Medicare coverage extends to mounting systems necessary to place the SGD, switches or other access devices within the reach of or otherwise appropriately positioned for the Medicare beneficiary. Medicare coverage also extends to accessories for speech generating devices that will provide access to Medicare beneficiaries with physical or sensory impairments in addition to severe speech impairment. Examples include: key-guards, optical head pointers, joysticks, switches, eye tracking accessories that will provide access to an SGD but will not control another device, and wheelchair integration devices.

Comment # 8: Maintain the Option for Coverage of Either a Dedicated SGD or for SGD Software

In the 2001 NCD, Medicare recognized that both a dedicated SGD and SGD software that would be loaded onto a device the client already owned were appropriate for coverage. These choices must be maintained.

For some clients, SGD software, not a dedicated computer-based or purpose built SGD, will satisfy the person's daily communication needs. The SGD software may run on existing computer the Medicare beneficiary already owns, allowing for unique customization and resource efficiency for the beneficiary. This option also is cost-efficient for Medicare.

However, other Medicare beneficiaries with speech impairments can only get their communication needs met with a dedicated SGD. This funding benefit should also be maintained.

- Dedicated built-for-purpose SGDs are configured and engineered to provide specific features that meet the needs of a variety of communication challenges not satisfied by SGD software alone.
- Dedicated SGDs are built to be durable, more easily heard in loud environments with high output speakers, easily mounted on wheelchairs and tables, and provide robust language representation options.
- Dedicated SGDs are adaptable for alternative access methods, such as head control, eye control, or switch scanning. Many people with communication impairments have co-occurring severe physical disabilities that leave them unable to use a standard mouse, keyboard, or touch screen. These individuals would be unable to use SGD software on a computer or tablet without alternative access options.
- Dedicated SGDs arrive ready to use as a packaged DME product, whereas SGD software requires the purchase of hardware that may be unaffordable or stress the financial resources of many Medicare beneficiaries.

For these Medicare beneficiaries, who have physical impairments that now or that may progress to require use of mounting systems and access aids, and who lack the resources to purchase necessary hardware with their own funds, covering only SGD software and not dedicated SGDs would result in an inability to communicate. To avoid these harmful restrictions, CMS must continue to allow funding options for both dedicated SGDs and SGD software.

To achieve this outcome, the MIT recommends no changes to the existing text of the 2001 NCD. On this topic, the 2001 NCD text already includes the appropriate scope of SGD coverage.

Section 6: MIT Recommendations for Revision of 2001 NCD Text

The foregoing comments offered by the MIT support the following recommended changes to the text of the 2001 NCD's. It is the MIT's recommendation that the outcome of the CMS

reconsideration of the 2001 NCD for SGDs be completed as soon as possible and that a revised NCD be issued that states the following:

[The text that follows is identical to the proposed revisions stated in the Executive Summary]

[The proposed changes and additions to the existing National Coverage Decision for SGDs, are identified in red. Deletions to the existing text are ~~crossed out~~]

National Coverage Decision for Speech Generating Devices

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 dedicated speech device, used solely by the individual who has a severe speech impairment;
- May be a dedicated personal computer or computer based device and may be based on off-the-shelf hardware or purpose built hardware;
- May have capabilities and features such as wireless, Bluetooth connectivity, and others necessary for proper device operation and conveyance of full benefits as SGDs;
- May have capabilities beyond speech generation that do not affect the primary and customary use of the device as a speech generating device and are generally not useful to individuals without illness or injury, such as environmental control and phone control;
- May have digitized speech output, using prerecorded messages, less than or equal to 8 minutes recording time;
- May have digitized speech output, using pre-recorded messages, greater than 8 but less than or equal to 20 minutes recording time;
- May have digitized speech output, using pre-recorded messages, greater than 20 but less than or equal to 40 minutes recording time
- May have digitized speech output, using pre-recorded messages, greater than 40 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.

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 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 than non-medical function.
- ~~Laptop computers, desktop computers, or PDA's which may be programmed to perform the same function as a speech generating device, are noncovered 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.

Speech Generating Software

Medicare coverage extends to ~~May be~~ software that allows a personal computer or computer-based device ~~laptop computer, desktop computer or personal digital assistant (PDA)~~ to function as a speech generating device.

Speech Generating Device Accessories

In addition to speech generating devices, Medicare coverage extends to mounting systems necessary to place the SGD, switches or other access devices within the reach of or otherwise appropriately positioned for the Medicare beneficiary. Medicare coverage also extends to accessories for speech generating devices that will provide access to Medicare beneficiaries with physical or sensory impairments in addition to severe speech impairment. Examples include: key-guards, optical head pointers, joysticks, switches, eye tracking accessories that will provide access to an SGD but will not control another device, and wheelchair integration devices.

Speech Generating Device Upgrades

Speech generating devices may be upgraded pursuant to § 1834 of the Social Security Act at Medicare beneficiary expense to provide access to capabilities or features that are not medically necessary, such as “unlocking” to provide access to non-speech communication methods, including internet and e-mail access.

Conclusion

We thank you for the opportunity to provide these comments and conclude with an offer of whatever assistance you may desire including hands-on SGD demonstrations, discussion of the professional literature or practice, or the role of SGDs in the lives of Medicare beneficiaries with complex communication needs. Please contact me you have any questions.

Respectfully submitted,

ON BEHALF OF THE MEDICARE IMPLEMENTATION TEAM

Lewis Golinker, Esq.
Director

Attachments: Exhibits 1 and 2



MAY 4 2001

7500 SECURITY BOULEVARD
BALTIMORE MD 21244-1850

Mr. Lewis Golinker, Esq.
Director
Assistive Technology Law Center
202 East State Street, Suite 507
Ithaca, New York 14850

Dear Mr. Golinker:

I am responding to your April 25, 2001 letter regarding "Computer and PDA-Based AAC Devices (SGDs)". Your letter requests that "HCFA eliminate potential confusion regarding the coverage of these devices by revising the National Coverage Decision on Speech Generating Devices, CIM Section 60-23 (Nov. 30, 2000)."

Based on an internal HCFA review of CIM (Coverage Issues Manual) Section 60-23 and a telephone conversation between you and two members of my staff (Walt Rutemueller and Lynn Riley) on April 25, 2001, we are all in agreement that CIM Section 60-23 does not require a revision. However, to ensure that the policy is interpreted consistently by all parties mentioned in your letter ("DMERC medical directors", "Medicare + Choice providers", and "Medicaid" agencies), as well as beneficiaries, we are providing the following interpretive clarification of the CIM policy:

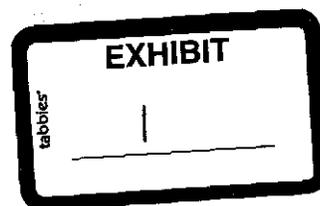
Computer-based and PDA-based AAC devices/speech generating devices are covered when they have been modified to run only AAC software.

I hope that this clarification eliminates any potential confusion regarding the coverage of speech generating devices.

Sincerely,

Thomas E. Hoyer
Director
Chronic Care Policy Group
Center for Health Plans and Providers

cc: Paul Hughes, M.D., DMERC Region A



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Adrian Oleck, M.D., DMERC Region B
Paul Metzger, M.D., DMERC Region C
Robert Hoover, M.D., DMERC Region D
Sean Tunis, M.D., M.Sc., OCSQ
Tom Gustafson, CHPP
Tim Hill, OFM

EXHIBIT 2

SGDs Receiving Coding Verification 2001 – 2013

SGD Model	Manufacturer	HCPCS Code	Effective Date
Accent 1000	PRC	E 2510	02/28/2013
Accent 1200 Integrated version	PRC	E 2510	05/17/2012
Accent 1200 standard version	PRC	E 2510	05/17/2012
Accent 700	PRC	E 2510	12/20/2012
Accent 800-D	PRC	E 2510	12/04/2012
AlphaTalker 11	PRC	E 2510	05/16/2001
ChatBox	PRC	E 2510	05/16/2001
Dedicated Alt-Chat	PRC	E 2510	08/04/2011
Dedicated Chat-PC	PRC	E 2510	08/04/2011
Delta Talker	PRC	E 2510	05/16/2001
ECO 2	PRC	E 2510	08/02/2011
Edge Talker	LC Technologies	E 2510	09/23/2009
FRS Comlink LT3G	FRS Custom Solutions	E 2510	04/21/2011
FRS Comlink Proslate 10	FRS Custom Solutions	E 2510	01/02/2013
FRS Comlink Proslate 4	FRS Custom Solutions	E 2510	01/02/2013
FRS Comlink Proslate 8	FRS Custom Solutions	E 2510	06/11/2013
FRS Comlink ST3G	FRS Custom Solutions	E 2510	04/21/2011
FRS Comlink Ultra	FRS Custom Solutions	E 2510	04/21/2011
Lightwriter	Tobii-ATI	E 2510	11/03/2010
Lightwriter SL40 Connect	Tobii-ATI	E 2510	05/06/2011
LINGGO 1000	Lingraphicare America	E 2510	08/01/2011
LINGGO 700	Lingraphicare America	E 2510	08/01/2011
Lingraphica	Lingraphicare America	E 2510	11/22/2010
AllTalk	Lingraphicare America	E 2510	12/09/2011
MiniTalk	Lingraphicare America	E 2510	04/17/2013
Logovox	Logovox Systems	E 2510	01/01/2004
My Tobii P-10	Tobii Technology	E 2510	10/27/2006
NovaChat 5	Saltillo	E 2510	12/11/2012
NovaChat 5-D Plus	Saltillo	E 2510	12/11/2012
NovaChat 5-Plus	Saltillo	E 2510	12/11/2012
NovaChat 10	Saltillo	E 2510	05/14/2012
NovaChat 10-D Plus	Saltillo	E 2510	05/14/2012
NovaChat 10-Plus	Saltillo	E 2510	05/14/2012
NovaChat 7	Saltillo	E 2510	07/24/2012
NovaChat 7-D Plus	Saltillo	E 2510	07/24/2012
NovaChat 7-Plus	Saltillo	E 2510	07/24/2012
Pathfinder	PRC	E 2510	05/16/2001
Quick Glance 2	EyeTech Digital Systems	E 2510	11/14/2005
Quick Glance SGD	EyeTech Digital Systems	E 2510	11/09/2006
Sidekick	PRC	E 2510	05/16/2001

EXHIBIT

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Survivor Speech Companion System	O'Brien Technologies	E 2510	07/30/2009
Tobii C-12	Tobii-ATI	E 2510	04/21/2010
Tobii C-15	Tobii-ATI	E 2510	03/16/2011
Tobii C-8	Tobii-ATI	E 2510	04/21/2010
Touchtalk 1000	Lingraphicare America	E 2510	09/15/2011
Touchtalk 700	Lingraphicare America	E 2510	09/15/2011
Vanguard	PRC	E 2510	05/16/2001
Vanguard Plus	PRC	E 2510	08/02/2011
Vantage	PRC	E 2510	05/16/2001
Vantage Light	PRC	E 2510	08/02/2011
WEGO Dedicated SGD	Talk To Me Technologies	E 2510	04/17/2013
Words for Live Nov Edition	PRC	E 2510	09/10/2013

Data Source: PDAC; Prentke Romich Company