



Funding for SGDs in 2015, Part II: Latest Updates and Implications for the AAC Community

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Part I Recap: Medicare SGD Coverage 2001-2013 (The ‘Golden Age’)

- Medicare SGD Coverage Guidance “2001 National Coverage Decision (NCD)” supports SGD coverage when needed to meet daily communication needs. All diagnoses are covered. SLP evaluation report and recommendation controls SGD access.
- 2001 NCD initially excluded computer based SGDs. Corrected 5/2001. All hardware types used as SGDs are eligible for Medicare coverage and payment, if “dedicated speech devices.”
- 2001 NCD had no definition of “speech.”
- 2001 NCD allowed SGDs to have capabilities beyond speech, to include environmental and phone control and full computer features, including internet access.
- 2001-2013 access to SGD capabilities beyond speech was called “unlocking.” Unlocking occurred at beneficiary request and for a small additional charge, paid by the beneficiary. Unlocking could occur at any time after device delivery.
- 2001-2013 Medicare coverage included SGD accessories, also including eye tracking accessories.

Medicare SGD Coverage 2013-2014: Trouble Begins

- Eye Tracking Accessories
 - In late 2013, a proposal was submitted for a new code specifically for eye tracking accessories. For general computer access, *not* for SGDs. Rejected. Rules state clearly Medicare will pay only for accessories that connect to DME items; computers are not DME.
 - In late 2013, Medicare begins denying payment claims for SGD eye tracking accessories.
- Capped Rental
 - Even at low volume (2000 SGDs/year) SGDs' very high per unit cost causes Medicare to take notice. One SGD code (E 2510) is one of the most costly among all Medicare DME.
 - In 2013, Medicare reinterpreted the law governing how Medicare pays for DME items. Its goal was to save money. As a result SGDs (and about 100 other items) were re-classified for Medicare payment as "capped rental" DME, effective April 1, 2014
 - In early 2014, Medicare rejects requests to exempt SGDs from capped rental or to delay the start date for capped rental.
 - Capped rental payment for SGDs went into effect 4/1/14.

Medicare SGD Coverage 2013-2014: Trouble Continues

- Device Functionality
 - In late February 2014, Medicare issues a mis-named “coverage reminder” for SGDs.
 - Rather than re-state current SGD coverage policy, it made substantial changes.
 - Computer based SGDs are not covered.
 - SGDs can have no functional capability beyond speech generation.
 - Environmental control; phone control; and capability for unlocking are all expressly prohibited. Each is a disqualifying feature for Medicare coverage and payment.
 - Unlocking for non-speech generating uses is prohibited for the life of the device.
 - Mandatory coding verification must occur before September 1, 2014.

Medicare SGD Coverage

2014-15: Additional Developments

April through late August, 2014: efforts were made to persuade Medicare managers to withdraw the coverage reminder. Medicare staff refused to do so.

Late August, 2014: Medicare delayed the deadline for “coding verification” from 9/1 to 12/1/14. This change had no substantive effect on Medicare beneficiaries.

September 11, 2014: 200 Members of Congress wrote to Medicare to suggest ways to solve the SGD coverage issues. Medicare did not take the hint.

November 6, 2014: Medicare (a) withdrew the “coverage reminder,” (b) eliminated the coding verification requirement, and (c) announced it was going to “reconsider” the NCD for SGDs. The expected completion date is 7/31/15. These changes have had no substantive effect on Medicare beneficiaries. Even with the “coverage reminder” withdrawn, the SGD manufacturers still refuse to allow SGDs to be “unlocked” during capped rental.

Early December, 2014: Reconsideration comes with a 30 day initial comment period. Almost 2,300 comments were submitted.

December 17, 2014: Medicare responded to the 9/11 Congressional Letter answering none of the points raised. Answers will come, if at all, at the end of the reconsideration process.

Late January, 2015: the so-called *Steve Gleason Act* was introduced in Congress to eliminate SGD capped rental and re-define Medicare “DME” to include SGD eye tracking accessories.

April 8, 2015: Webinar Session I: “SGD Funding Updates and Implications” was delivered.

Medicare 2015: Latest Update

- April 29, 2015: Medicare releases draft revised National Coverage Decision for SGDs to replace 2001 NCD for SGDs;
- May 29, 2015: deadline for submission of comments to draft revised NCD for SGDs
- Steve Gleason Act: Re-written, passes the U.S. Senate

Draft NCD to Replace 2001 NCD for SGDs

- Overview: the draft NCD restores the full scope of Medicare SGD coverage – as to devices, capabilities and features – that existed from 2001-2013. It also “expands” coverage by redefining “speech” and making it much easier to access SGDs’ non-face-to-face communication features and their non-communication capabilities and features.
- If adopted as a final guideline as written, Medicare SGD coverage since 2001 will have gone through 3 phases:

2001-2013	2014	Draft NCD (2015 ++)
All SGD types are covered	No computer based devices covered	All SGDs types are covered
Devices must be dedicated when delivered	Devices must be dedicated when delivered;	“Dedicated” is not used to describe SGD function; devices must be limited to speech when delivered
“Dedicated” means device will support F2F communication	“Dedicated” means device will support F2F communication	“Speech,” <u>expanded</u> to include F2F communication as well as communication by text, e-mail or telephone
Devices can have additional features such as environmental control; phone control and general computer functions; access to these features is by “unlocking,” performed at client request and expense	Devices can have no additional features and can have no capability other than speech generation; capability for “unlocking” is expressly prohibited	Devices can have additional capabilities and features; access to these non-communication features is by use of a routine Medicare form called an Advanced Beneficiary Notice (ABN); ABN substitutes for “unlocking” and “upgrades”
Unlocking can occur at any time after device delivery	Devices can never be unlocked	ABN can be used at any time after device delivery

SGD Hardware: Types of Devices Covered

- The 2001 NCD initially excluded computer based devices from coverage, but that limitation was eliminated in May 2001. Any hardware that can be made to function as a dedicated speech aid was eligible for Medicare coverage and payment as an SGD. All SGDs available in 2001 and all hardware used as SGDs since then have been eligible for Medicare coverage and payment.
- In 2014, the “coverage reminder” re-stated the initial exclusion of computer based devices from Medicare coverage and payment.
- The draft NCD eliminates all references to SGD hardware, focusing solely on features Medicare will cover and pay for, and those it will not. This approach will allow coverage and payment for all hardware that can meet the Medicare requirements to be an SGD, including hardware developed and introduced for use in the future.

“Dedicated” Devices

- The 2001 NCD required SGDs to be “dedicated speech aids.” No definition was provided but this phrase was understood initially to refer only to “purpose built” SGDs, as compared to computer-based devices, which were excluded. “Dedicated” also required SGDs, when delivered to clients, to offer access to SGD software only.
- In May 2001, the NCD was clarified to allow Medicare coverage and payment for “dedicated computer-based devices.” Thereafter, the meaning of “dedicated” narrowed to its functional limitation only: at delivery, SGDs must run only SGD software.
- The 2014 “coverage reminder” restated that SGDs must be “dedicated” and reinstated its original, dual meaning. Computer based SGDs were again excluded. And, it stated: “*dedicated device means that the SGD must be a device limited solely to the generation of speech....*” (emphasis in original).
- The draft NCD introduces a new approach. It does not include the word “dedicated.” Instead, identifies the capabilities and features of SGDs it is willing to pay for, and those it is not. Devices that meet this requirement are eligible for Medicare coverage and payment. CMS explained this change as follows: “*As long as the [SGD] is limited to use by patients with severe speech impairment, and is primarily used for the purpose of generating speech, we do not believe it is necessary for a [SGD] to be dedicated only to speech generation in order to be considered DME.*”

Does the Omission of “Dedicated” in the Draft NCD Change Anything?

- Since 2001, some people have stated the reference to “dedicated speech aids” in the 2001 NCD substantively limits SGD choices, impeding access to current technologies; and limits SGD capabilities.
- In response to the draft NCD, several comments applauded the elimination of “dedicated” and asked Medicare to add the reasoning behind the change to the text. *“As long as the [SGD] is limited to use by patients with severe speech impairment, and is primarily used for the purpose of generating speech, we do not believe it is necessary for a [SGD] to be dedicated only to speech generation in order to be considered DME.”*
- On review, the statements about dedicated devices are wrong. Since May 2001, “dedicated” had no **device choice** effect. All types of computer-based devices were covered. From the beginning, “dedicated” never had a **functional** effect. “Dedicated” described only how SGDs had to be *delivered*, not how they had to function. Immediately after delivery, clients could request their devices be “unlocked” to access additional device features.
- The draft NCD does not state a substantive change in that Medicare policy. It identifies features that are covered and features that Medicare won’t pay for. Covered features relate to the expanded definition or scope of “speech.” Non-covered features include SGDs’ non-communication capabilities and features. For coverage purposes, SGDs now will be limited to speech, where before they were “dedicated.” But immediately upon delivery, based on an ABN, access will be provided to additional SGD features, where before they were “unlocked.”

SGD Covered Features: Definition of “Speech”

- The 2001 NCD has no definition of “speech.” But it was universally understood that “speech” meant face-to-face (F2F) communication. In 2001, SGDs had the capability of supporting communication by e-mail, texting and telephone, but these were not pursued as standard features of devices.
- The 2014 “coverage reminder” did not define “speech” but limited SGDs to “speech generation” only. It was universally assumed that “speech” meant F2F communication.
- The draft NCD provides a specific definition for “speech” and ***expands*** the assumed meaning that existed since 2001. “Speech” will now include actual speech to support F2F communication as well as communication by text, e-mail and telephone. The draft NCD calls this “remote” communication. It states: *“We are proposing the expand the types and features of [SGDs] that would fall within the DME benefit category.”* Specifically, *“[o]ther covered features of the device [in addition to speech generation for F2F communication] include the capability to generate email, text or phone messages to allow the patient to ‘speak’ or communicate remotely....”*
- In addition, the draft NCD states clearly that other SGD features that aid their function as SGDs are covered. *“Other covered features include ... the capability to download updates to the covered features of the device from the manufacturer or supplier of the device.”*

Other SGD Capabilities and Features: Covered or Not Covered?

- The 2001 NCD identified specific capabilities and features that would *disqualify* devices from Medicare coverage and payment. Considered as a whole, they included any “*software for purposes other than speech generation.*”
- The 2014 “coverage reminder” was far more specific and expansive. It identified many capabilities and features as examples, but then stated that devices with **any capability** “*exceeding the sole function of speech generation*” was *disqualifying*.
- The draft NCD takes a different approach. A small number of SGD capabilities and features are identified, but Medicare states simply that it will not cover or pay for them. Their presence is **not** *disqualifying* for the device. The list includes:
 - internet or phone services
 - any modification to a patient’s home to allow use of the SGD
 - specific features that are not used by the client to meet his or her functional speaking needs
 - any computing hardware or software not necessary to allow for generation of speech, e-mail, text, or phone messages,
 - hardware or software used to create documents and spreadsheets or play games or music and any other function a computer can perform that is not directly related to meeting the client’s functional speaking communication needs
 - Video communications or video-conferencing

Access to Non-Covered Features

- The 2001 NCD and the May 2001 computer-based device clarification do not mention that SGDs can have additional capabilities and features or how or when clients can access them.
- From 2001-13 this omission had no effect. Medicare staff knew that SGDs had several additional capabilities, i.e., support for environmental and phone control, internet access, and general computer functions. No concern was expressed because upon device delivery SGDs became client property. Medicare policy allows client owned equipment to be modified any way clients wished, at their own expense. We called the procedure to access these additional features “*unlocking*.”
- The 2014 “coverage reminder” completely reversed Medicare policy. It identified specific features that were prohibited. Then, it stated devices with the capability for any features beyond speech generation were disqualified. Finally, it added, gratuitously, that the “capability for unlocking” was prohibited.
- Medicare withdrew the “coverage reminder” in Nov. 2014, but the SGD manufacturers did not return to the practices of 2001-2013. In April 2014, Medicare changed SGDs to “capped rental” DME, one effect of which is to delay client ownership of devices for 13 months after delivery. The manufacturers believed “unlocking” could not occur during capped rental without express Medicare consent. CMS was asked countless times, but the agency *never* responded. Specific authority from the Medicare statute was cited: it authorizes DME “upgrades,” device features that Medicare does not recognize as its responsibility to pay for. Congress stated upgrades are available for rented as well as purchased DME.
- The draft NCD both restores SGD capability for additional features and makes access to them much ***easier***. No capabilities or features are prohibited or disqualifying for the device. Instead, the text states simply and plainly that SGD manufacturers or suppliers should identify all device features Medicare won’t pay for on a standard form called an Advanced Beneficiary Notice (ABN) and provide that to all clients. The ABN tells clients that Medicare won’t pay for the listed capabilities or features and that client access to them will be provided at client expense. The NCD draft does not reference “unlocking” or “upgrades,” although an ABN *is* the form required to access DME upgrades.

Environmental Control Coverage

- The 2001 NCD did not mention the capability of SGDs to support environmental control, i.e. to generate a signal that can control an appliance, doors, windows, blinds, thermostat, etc. Medicare staff knew SGDs had for many years included the ability to generate an electronic signal that can be used for environmental control, but did not object. This feature was of only ancillary importance: it was not the “primary or customary” use of the device and therefore, was not relevant to Medicare coverage.
- The 2014 coverage reminder reversed that Medicare policy. It singled out environmental control as a feature that will disqualify a device from Medicare coverage and payment.
- The draft NCD does not mention environmental control. Instead, it states that Medicare will not pay for “*modifications to a patient’s home,*” which also is necessary for environmental control to work, but payment for *those* costs had never been sought from Medicare.
- The omission of environmental control from the draft NCD does not mean it cannot be offered. Instead, it should be treated as any other non-covered feature that can be offered if identified on an ABN and requested by the client.

SGD Software Coverage

- The 2001 NCD included coverage of “*software that allows a laptop computer, desktop computer or personal digital assistant (PDA) to function as a speech generating device.*” Medicare created a specific DME code for SGD software: E 2511.
- The 2014 “coverage reminder” re-stated that SGD software is covered but also stated a new exclusion: “*accessories/peripherals for use on a non-dedicated device running SGD software are non-covered.*”
- The draft NCD restores SGD software coverage to what it had been between 2001 and 2013. It updates the vocabulary to state that Medicare coverage and payment will extend to: “*software that allows a computer or other electronic device to function as a speech generating device.*” There is no additional limitation on Medicare coverage of accessories or mounts needed by clients using their own device plus SGD software.

SGD Issues the Draft NCD Does Not Address

- Capped Rental

- The draft NCD eliminates the limitation on SGD function associated with capped rental. Use of an ABN will allow access to all SGD capabilities and features during capped rental. ABNs are used to allow access to DME upgrades; SGD “unlocking” has been viewed as synonymous with “upgrades;” “upgrades” are authorized by statute to be available for rented or purchased equipment.
- But the draft NCD does not eliminate the risk of device loss for clients who begin nursing facility or hospice care during the capped rental period.
- Medicare has said that only Congress can cause SGDs to be re-classified out of capped rental.
- The *Gleason Act* includes a provision that will remove SGDs from “capped rental.” However, before it passed the Senate, the re-classification was changed to be effective for only 3 years.

- Access Aids: Eye Tracking Accessories

- The 2001 NCD did not refer to SGD accessories. Their coverage is confirmed in another Medicare guideline.
- The draft NCD does not refer to them either.
- The eye tracking accessories’ coverage dispute continues. However, these accessories continue to be provided, and are not subject to the capped rental payment rule. No client who needs eye tracking has been unable to get one.
- The *Gleason Act* includes a provision that will redefine DME in the Medicare statute to include SGD eye tracking, but it is unknown whether this change will have any effect on the current coverage dispute.

What Happens Next?

- The draft NCD was released on April 29. Medicare offered the opportunity for comments to be submitted by May 29. Approximately 220 comments were submitted as compared to almost 2,300 that were submitted when the NCD reconsideration began.
- Medicare will now review the comments, decide if the draft should be changed in any way, and then issue a final guideline that will replace the 2001 NCD.
- Medicare stated when the reconsideration began that it expected to complete this process by July 31, 2015. That date is subject to change at Medicare's discretion. Also, it is unknown whether "completion" of the reconsideration process means the new NCD will be effective on the same date.
 - Medicare announced it was withdrawing the "convenience item" non-coverage NCD in April 2000, and issued the 2001 NCD in early November, 2000, but SGD coverage and the then-new NCD was not effective until January 1, 2001.
- The Gleason Act may or may not pass. If it passes, the 3-year re-classification of SGDs from capped rental will become effective on October 1, 2015. The addition of eye tracking to the DME definition will be effective Jan. 1, 2016.

If the Draft is Adopted as Final, How will the New NCD Work?

- Interplay with Capped Rental
 - If the NCD becomes effective while SGDs are still subject to capped rental, all *new* device orders after the NCD's effective date will be subject to the new NCD. All of these devices will be subject to the ABN provision in the NCD: upon client request, their SGDs will be able to provide immediate access to non-covered capabilities and features.
 - The same opportunity should apply to all existing capped rental devices. Upon client request, they should be modified to provide access to non-covered capabilities and features or they should be exchanged for a device with those capabilities. No Medicare guideline says a client must follow the coverage rules applicable at the time capped rental began. Also, use of an ABN to access non-covered features always has been an available option: the SGD manufacturers just didn't offer it while the NCD reconsideration was pending.
- User-Facing Camera
 - The draft NCD singles out video communication and video conferencing as non-covered features. This creates an issue for SGD manufacturers: what to do with the user-facing camera? It is unreasonable to expect it to be physically removed. Instead, it is far more likely it will be disabled and then listed on an ABN as an available, non-covered feature upon client request. Or, it may be offered as an available device feature, but listed on an ABN as one that Medicare won't pay for. The manufacturer does not have to then charge an additional fee for the camera: Medicare rules allow DME "upgrades" to be offered without charge.

If the Draft is Adopted as Final, How will the New NCD Work? - 2

- Internet Access

- The draft NCD states that Medicare will not cover or pay for “internet or phone services.” This reference is to the charges for an internet services provider and for a phone line.
- The draft NCD also includes texting and e-mail under the redefinition of “speech” and both can be offered as standard SGD features of SGDs. Either can be accessed through internet based services.
- The draft does not state *how* SGD manufacturers will make these expanded “speech” capabilities or features available. That choice is up to them. Providing internet access is one alternative.
- Even if the draft NCD is interpreted to not allow SGDs to provide internet access as a standard feature, it still can be provided, as a non-covered feature subject to an ABN.
- If SGDs offer internet access, they also will have the capability to download additional software and support general web-searching. SGD manufacturers may list download and “search” capabilities on an ABN as a non-covered feature.

Conclusion

- If adopted as a replacement for the 2001 NCD, the draft NCD will restore the scope of Medicare SGD coverage that existed between 2001-2013, and will make it easier for clients to access SGDs' non-face-to-face communication features and non-communication features.
- If adopted, the draft NCD will eliminate all vestiges of the 2014 “coverage reminder.”
- If adopted, Medicare SGD coverage criteria will again be a *positive* model for other funding programs to copy for their own use.
- If the draft text is adopted as a replacement for the 2001 NCD, it cannot go into effect soon enough.

Follow Up Information

- The draft NCD and a memo reviewing its content are both posted at www.patientprovidercommunication.org.
- The slides from Session I are posted for download and an audio recording of Session I is posted for review at <https://www.isaac-online.org/english/news/webinars/>
- Join USSAAC! <http://www.ussaac.org/memberships.cfm>
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- Let us know what you think and ideas for future topics and events
- Thank you!

