

FIRM / AFFILIATE OFFICES

Abu Dhabi	Milan
Barcelona	Moscow
Beijing	Munich
Boston	New Jersey
Brussels	New York
Century City	Orange County
Chicago	Paris
Doha	Riyadh
Dubai	Rome
Düsseldorf	San Diego
Frankfurt	San Francisco
Hamburg	Shanghai
Hong Kong	Silicon Valley
Houston	Singapore
London	Tokyo
Los Angeles	Washington, D.C.
Madrid	

LATHAM & WATKINS LLP

December 4, 2014

VIA EMAIL

CAGinquiries@cms.hhs.gov

Dr. Subash Duggirala
Lead Medical Officer
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Mail Stop C5-02-23
Baltimore, MD 21244

**Re: National Coverage Determination on Speech Generating Devices
Comments on Benefit Category Determination NCD**

Dear Dr. Duggirala:

Thank you for the opportunity to address the internally-generated reconsideration of the national coverage determination (“NCD”) for Speech Generating Devices (“SGDs”).¹ The stakeholders listed below have discussed and agreed upon the attached “Appendix A” revisions to the current NCD. We applaud the Agency for recognizing the need to reconsider the NCD and urge that this be done in a manner that ensures continued access to medically-indicated SGDs, which are relied upon by some of the most vulnerable Medicare beneficiaries, including those with amyotrophic lateral sclerosis (“ALS”), autism, cerebral palsy, aphasia from stroke and traumatic brain injury.

American Speech-Language-Hearing Association
The Amyotrophic Lateral Sclerosis Association
Independence Through Enhancement of Medicare and Medicaid (“ITEM”) Coalition²
Lingraphica
Prentke Romich Company
Saltillo Corporation
Tobii-Dynavox Technology, Inc.

¹ See Medicare National Coverage Determinations Manual (Pub. 100-03), Chapt. 1, Pt. 1, § 50.1.

² The full list of organizations making up the membership of the ITEM Coalition is located at <http://itemcoalition.org/about/members/>.

As part of its reconsideration process, on November 6, 2014, the Centers for Medicare & Medicaid Services' ("CMS's") published a notice of the Agency's intent "to address coverage of devices that generate speech as well as other forms of communication."³ The notice states 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," including the use of the devices "to generate text and email messages for the purpose of communicating with their caregivers and physicians." As we explain further below, to ensure the NCD does not threaten Medicare coverage for the majority or all of the SGDs on the market, we are asking that the fourteen-year-old NCD on SGDs be revised and clarified in an appropriate manner, to eliminate current ambiguities in its language.

Specifically, the NCD should make clear that devices that add functionality and features (in addition to those needed for speech generation) are not rendered non-covered simply because of such additions. Instead, the functionality and features sought by patients should be treated as an upgrade, or as otherwise appropriate, so that patients have a right to purchase them on a self-pay basis. This would also permit the speech-impaired individual to choose to "unlock" a device to enable additional uses.

Further, manufacturers using existing platforms or operating systems when developing their SGDs should not be required to redesign products. Such a requirement to have them rebuilt with no resulting functional advantage serves no useful purpose. The NCD should expressly state that the use of existing platforms or operating systems is permissible, as long as the device is designed for and used solely by the individual with a speech impairment.

We provide at Appendix A the suggested changes we are proposing for the needed clarification in the current NCD. Below, we discuss the rationale for the proposed clarifications.

A. NCD Changes Should Be Made to Align its Language with the Purpose of SGD Coverage—to Meet the Needs of Speech-Impaired Individuals

On April 26, 2000, CMS established a national coverage policy regarding augmentative and alternative communication ("AAC") devices for speech impairment.⁴ The Agency determined at that time that its previous conclusion that these devices were convenience items should be reversed; and the Agency confirmed it had "now decided that AAC devices are a Medicare benefit in the category of durable medical equipment (DME)."⁵ Speech-impaired individuals have greatly benefited from this critical policy step. We are seeking at this juncture the additional steps to be taken by CMS to ensure that the policy is continued and implemented in a meaningful way.

³ CMS opened the 30-day comment period for the reconsideration through December 6, 2014.

⁴ See Decision Memo for Augmentative and Alternative Communication (AAC) Devices for Speech Impairment (CAG-00055N), available at <http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=8&fromdb=true> (accessed Nov. 24, 2014).

⁵ *Id.*

CMS involvement in this benefit has remained critical since it became effective January 1, 2001, when CMS added a new section 60-23 to the DME portion of the Coverage Issues Manual to define the coverage for the AAC devices—titled “Speech Generating Devices.”⁶ At that time, following raised concerns that the provision may be interpreted to foreclose technology designed using the hardware described, on May 4, 2001, CMS clarified the Agency’s interpretation to underscore that computer-based and PDA-based SGDs may in fact be covered.⁷ In other words, the DME benefit extended to devices that used components on the market, but these components were modified as part of a device designed specifically for the purpose of speech-generation. At this juncture, further clarification is needed within the text of the NCD to ensure continued access to the majority (if not all) the devices on the market.

Significantly, the national and local Medicare coverage policies, which are currently in effect, provide important support for the clarification we are proposing. The Medicare local coverage determinations for SGDs already recognize the clinical needs of the patient and the requirement for, among other things, an assessment by a speech-language pathologist of current communication impairments and whether the individual’s daily communication goals can be achieved with a specifically-selected device and accessories. As we further explain in the next two sections, the NCD should now more precisely account for the manner in which current SGDs are designed and built by well-established and well-regarded manufacturers, as well as how their technology has evolved. In addition, the NCD should expressly account for the manner in which SGDs are used by speech-impaired individuals with severe functional limitations, including their election of additional functionality and features.

B. Additional Functionality and Features Should Not Render an SGD Non-covered

Some speech-impaired individuals opt for features that enable them to overcome not only the physical and linguistic barriers to speech, but also to participate more fully in other aspects of life. For example, the language interface that allows an individual with aphasia to compose a message to be spoken audibly could also enable her to compose a message to be transmitted on a phone or in an email. In its November notice of reconsideration, CMS acknowledged the significance of such text and email generation, so that individuals can communicate with their caregivers and physicians. Indeed, this is not unlike a spoken word by telephone. Even if CMS does not cover or otherwise make payment for certain perceived or actual non-speech functionality, therefore, it is important for the agency to acknowledge expressly that such capabilities would not disqualify the device from coverage. To do otherwise would amount to both a disservice to beneficiaries relying on the device for their speech impairment and contradict well-established congressional directive and CMS policies on the ability to purchase upgrades or deluxe features.

⁶ See <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R132CIM.pdf> (accessed Nov. 24, 2014).

⁷ Letter from Thomas E. Hoyer, Director, Chronic Care Policy Group, HCFA to Mr. Lewis Golinker, Esq., Director, Assistive Technology Law Center (May 4, 2001) (“Computer-based and PDA-based AAC devices/speech generating devices are covered when they have been modified to run only AAC software.”). The letter copies the medical directors for the DMERCs A, B, C & D, the Office for Clinical Standards and Quality, the Director of the Office of Financial Management and the Director of the Center for Health Plans and Providers.

The focus in recent publications and articles published by CMS’s contractors on whether a device can be “unlocked” for certain functionality (specifically noting such functions as emails and word processing) overlooks the fact that in the first instance, individuals using the device are generally unable to use—or rarely, if ever, do use—the device for a purpose other than for speech generation or its facilitation. The Medicare beneficiaries who elect to have their devices unlocked represent a very small number of conditions, including by way of example, people with ALS or other impairments that do not affect cognitive function. Importantly, now that SGDs are classified as “capped rental,” for a person with ALS (one of the most likely Medicare patients to seek unlocking), the individual must otherwise wait to unlock the SGD until the device title is transferred from the supplier. In such cases, the progression of the condition may render moot any possible benefit of unlocking. Surely Medicare’s beneficiaries should not be required to forgo an SGD to obtain additional functionality. And surely Medicare’s beneficiaries deserve a more reasonable policy (and one that would come at no cost to the Medicare program).

We urge that features that permit the speech-impaired individual to benefit from additional functionality to assist with non-speech or other communication remain available to an individual seeking an “upgrade,” consistent with congressional mandates and CMS’s statutory authority for such a policy.⁸ Functionality or features that patients elect to purchase for their SGDs would in this way be paid separately. In turn, any unintended results of altogether eliminating the benefit for disabled individuals who may choose to elect the added functionality would be avoided.

C. Use of Existing Platforms Or Operating Systems Should Not Render SGDs Non-Covered

In addition to the clarification from CMS on the definition of SGDs,⁹ as part of the implementation of the NCD, local coverage policies were issued by the four Durable Medical Equipment Regional Carriers, for dates of service beginning July 1, 2001. The policies—initially included as part of the local medical coverage policies and now in the local coverage articles for SGDs—have at all times provided:

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 (DME).¹⁰

Though framed in the negative, the policies appear to recognize coverage for computers and PDAs that are modified or otherwise “dedicated” for speech generation. With respect to the longstanding NCD language that risks being interpreted as foreclosing coverage for essentially all SGDs on the market, we recommend that the NCD language be revised to more precisely account for not only the beneficiary’s election of functionality and features (as we note in the

⁸ 42 U.S.C. § 1395m(a)(19).

⁹ *see supra*, note 7.

¹⁰ *See, e.g.*, NHIC, Corp., Local Coverage Article for Speech Generating Devices (SGD) – Policy Article – July 2013 (A33770).

previous section), but also the manner in which currently-available SGDs are designed and built. In particular, current SGDs may use existing platforms or operating systems, yet remain “dedicated” devices—that is, true to the current NCD terms, such devices are designed specifically for speech generation. It is important to acknowledge expressly that use of existing platforms does not eliminate the fact that manufacturers design and build the device specifically for the speech-impaired individual, and this means more than simply loading software. As noted above, foreclosing the ability of well-established manufacturers serving Medicare beneficiaries for many years to use existing components in their design, may result in the inability of beneficiaries to obtain a quality SGD. We urge CMS to ensure this does not occur and to expressly clarify its NCD language accordingly.

* * * * *

Thank you for your consideration of our comments. Should you have any questions, please contact me at stuart.kurlander@lw.com or 202-637-2169.

Sincerely,



Stuart S. Kurlander
of LATHAM & WATKINS LLP

Enclosure

Appendix A

To address the above comments, the following revisions to the NCD for SGDs (Medicare National Coverage Determinations Manual (Pub. No. 100-03), § 50.1) are recommended:

“Benefit Category

Durable Medical Equipment

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

Indications and Limitations of Coverage

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

Definition of Speech Generating Devices

Speech generating devices are defined as speech aids that provide an individual who has a severe speech impairment with the ability to meet his functional speaking needs. Speech generating devices are characterized by:

- Being a device that produces speech by translating the user’s input into device-generated speech;
- Being a ~~dedicated speech~~ device; used solely by the individual who has a severe speech impairment;
- May have digitized speech output, using prerecorded messages, less than or equal to 8 minutes recording time;
- May have digitized speech output, using prerecorded messages, greater than 8 minutes recording time;
- May have synthesized speech output which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques; or
- May have synthesized speech output which permits multiple methods of message formulation and multiple methods of device access. ~~;~~

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

~~Devices that would not meet the definition of speech generating devices and therefore, do not fall within the scope of §1861(n) of the Act are characterized by:~~

- ~~Devices that are not speech devices, but are devices that are capable of running software for purposes other than for speech generation, e.g., devices that can also run a word processing package, an accounting program, or perform other than non-medical function.~~

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

- ~~A device that is useful to someone without severe speech impairment is not considered a speech generating device for Medicare coverage purposes.~~

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

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

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