

LATHAM & WATKINS LLP

May 13, 2014

VIA FEDEX & EMAIL

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**Re: Joint DME MAC Publication
Coverage Reminder – Speech Generating Devices**

Dear Mr Wilson:

We write on behalf of the organizations and companies listed below to request the immediate rescission of the Joint DME MAC Publication titled “Coverage Reminder – Speech Generating Devices” and first posted on February 27, 2014 (hereinafter “Coverage Reminder”).¹

Amyotrophic Lateral Sclerosis Association
American Speech-Language-Hearing Association
American Academy of Physical Medicine and Rehabilitation
International Society for Augmentative and Alternative Communication
National Disability Rights Network
The National Joint Committee for the Communication Needs of Persons with Severe Disabilities
The Rehabilitation Engineering and Assistive Technology Society of North America (RESNA)
United States Society for Augmentative and Alternative Communication
Medicare Implementation Team that Submitted the Formal Request for the National Coverage Decision for Augmentative & Alternative Communication Devices (1999)
Assistive Technology Law Center

Unlike its title, the Coverage Reminder makes substantive changes to longstanding coverage policy for speech generating devices, or SGD.² Unless withdrawn, these changes

¹ See, e.g., https://www.dmepdac.com/resources/articles/2014/03_31_14.html (accessed May 8, 2014).

would impose impediments to access to important medical devices for some of the most vulnerable Medicare beneficiaries, including those suffering from amyotrophic lateral sclerosis, or ALS. Moreover, given the September 1, 2014 effective date, action must be taken by June 1, 2014 to ensure that the Coding Reminder's requirement for submission of a new coding verification application, which has a 90-day window, is meaningfully addressed here.

As we demonstrate below, the Coverage Reminder is both inconsistent with the national coverage determination for SGDs, as further clarified by the Centers for Medicare & Medicaid Services' ("CMS's") central office in 2001, and with local coverage determinations for SGDs. Specifically, unless rescinded, the Coverage Reminder would revise current policies that recognize computer-based and PDA-based SGDs under the durable medical equipment ("DME") benefit. In 2001, CMS clarified that the Medicare program does indeed cover a computer or personal digital assistant ("PDA") that is modified with the appropriate functionality for SGDs.

With the Coverage Reminder, the current interpretations would be changed, such that any feature or capabilities exceeding the "sole" function of speech generation would not be covered. Further, products that have the additional functionality "locked" would not be covered if there are capabilities that can be "unlocked." This new interpretation contorts precedent without weighing its practical import. DME is defined as equipment that is "primarily and customarily used to serve a medical purpose" and the availability of additional features has not in other coverage policies eliminated the value of this primary medical function. Moreover, the additional features at issue here do provide a medical value by enhancing, for example, remote updates to the SGD software through wireless capabilities. Further, the features have been in place since 2001, when the products were demonstrated to CMS, and CMS acknowledged their value for coverage purposes. It is improper for a contractor to contradict national policy through a unilateral policy article. For these and the reasons further addressed in this letter, the below-listed organizations urge CMS to rescind its contractors' issuance.

Background of National and Local Coverage for SGDs

On April 26, 2000, CMS established a national coverage policy regarding augmentative and alternative communication ("AAC") devices for speech impairment.³ 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)."⁴ Effective January 1, 2001, CMS added a new section 60-23 to the DME portion of the Coverage Issues Manual to

² SGDs are Class II devices that are regulated by the Food and Drug Administration, as defined under 21 C.F.R. § 890.3710 (powered communication system used for medical purposes to transmit or receive information).

³ 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 May 8, 2014).

⁴ *Id.*

define the coverage for the AAC devices—titled “Speech Generating Devices.”⁵ (The NCD is found at section 50.1 of the current internet-based manual.⁶)

Notwithstanding that new coverage was conferred, as relevant to the current issue, the new NCD provided (and continues to provide) 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.

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 were in fact covered:

Based on an internal HCFA review of CIM (Coverage Issues Manual) Section 60-23 . . . 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.⁷

The letter was transmitted to the four medical directors responsible for coverage and claims processing for durable medical equipment. 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).⁸

⁵ See <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R132CIM.pdf> (accessed May 8, 2014).

⁶ See Medicare National Coverage Determinations Manual (Pub. 100-03), Chapt. 1, Pt. 1, § 50.1.

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) (emphasis in original). 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. A copy of the 2001 letter is attached at Tab 1.

Though framed in the negative, the policies recognize coverage for computers and PDAs that are “dedicated” for speech generation. With this guidance in place, the interpretations of the criteria for qualifying SGDs has remained consistent for approximately thirteen (13) years. Yet, on February 27, and March 19, 2014, the Durable Medical Equipment Medicare Administrative Contractors (“DME MACs”) and the Pricing, Data Analysis & Coding contractor (“PDAC”), respectively, each posted a joint DME MAC publication titled “Coverage Reminder – Speech Generating Devices,” which seeks to redefine what is meant by a “dedicated” device.⁹

Coverage Reminder – Speech Generating Devices

In stark contrast to the longstanding policies and their implementation, the ill-advised Coverage Reminder provides:

Dedicated device means that the SGD must be a device limited solely to the generation of speech, for use only by the individual who has a severe speech impairment.¹⁰

The Coverage Reminder forecloses functionality that has been part of the SGD benefit and recognized as such when the NCD and local coverage policies were first established. In relevant part, the Coverage Reminder articulates this change as follows:

This benefit does not extend coverage to the broader range of augmentative and alternative communications devices (AAC) that have capabilities exceeding the sole function(s) of speech generation such as (not all-inclusive): wireless and cellular communication capabilities, environmental control capability, non-speech generating software (e.g., games, word processing, email).

Products provided as a dedicated device that have the capability to be expanded with additional hardware and/or software or where additional functionality may be made available by “unlocking” hardware or software limitations do not meet the NCD requirement for classification as a dedicated device. Such non-dedicated devices are not eligible for coverage and should be coded A9270 (Noncovered item or service).¹¹

By both eliminating coverage for computers and PDAs and foreclosing coverage if the device is also capable of functions other than speech generation, the Coverage Reminder contradicts longstanding policies, as well as adds unnecessary expense and delays the ability to

⁸ See, e.g., NHIC, Corp., Local Coverage Article for Speech Generating Devices (SGD) – Policy Article – July 2013 (A33770).

⁹ See, e.g., https://www.dmepdac.com/resources/articles/2014/03_31_14.html (accessed May 8, 2014).

¹⁰ *Id.*

¹¹ *Id.*

continue marketing current technology. This also represents bad policy, as further addressed below.

I. THE COVERAGE REMINDER CONTRADICTS CMS'S 2001 CLARIFICATION RECOGNIZING COVERAGE OF COMPUTER AND PDA BASED DEVICES AS DME

The Coverage Reminder contradicts the CMS clarification issued in 2001 that permits the use of computer and PDA devices “when they have been modified to run only AAC software.”¹² CMS’s issuance of this 2001 clarification was the result of information provided to the Agency in correspondence, e-mail and telephone communications, as well as two in-person, hands-on demonstrations of SGDs that were laptop computer-based or PDA-based, but that had been modified to function as a device dedicated for speech generation. CMS recognized therefore that the functionality of an SGD is the key inquiry and classification as DME is appropriate when that functionality is met. CMS in 2001 also recognized that computer- and PDA-based devices are less costly options and Medicare beneficiaries receive equal benefits from such devices and other SGDs. Access also was a concern, primarily for people with ALS and other progressive impairments for whom the affected devices are recommended most frequently and for whom delays would mean no SGD access. The same holds true today.

If the Coverage Reminder is not rescinded, speech language pathologists will lose the ability to recommend several long-covered SGD models even if they are the most appropriate to meet recipients’ needs. Medicare beneficiaries, in turn, will not be provided the device most appropriate, or perhaps the only SGD appropriate to their needs. Critically, the SGD manufacturers, who must bear the cost of making changes to their products would be forced to develop more costly products. Yet, these product modifications would not translate to cost savings to patients or the Medicare program. In fact, the newly-developed products likely would come at a greater expense. It is therefore difficult to justify the Coverage Reminder as providing a benefit to the Medicare program.

II. THE COVERAGE REMINDER’S PROHIBITIONS OF ADDITIONAL FUNCTIONALITY AND UNLOCKING FEATURES ARE NOT GROUNDED IN ANY MEDICARE POLICY

Among the features listed in the Coverage Reminder as disqualifying a product for Medicare coverage are SGD components that enhance the speech-generating software program and those additional components that can be disabled or removed. This fails to recognize, by way of example, that a wireless capability enables SGD manufacturers to upgrade speech generating software, to troubleshoot problems reported by Medicare recipients, and to provide technical assistance and support. Wireless or “wi-fi” is an antenna that can be tuned by the SGD manufacturer to receive signals from specific sources only. Most dedicated SGDs, therefore, have and require wireless capability. The NCD for SGDs, in turn, does not state that the “sole” functionality of an SGD must be speech generation, in contrast to the Coverage Reminder. CMS staff recognized this fact in 2001 and no basis exists today to reach a different conclusion.

¹² Letter from Thomas E. Hoyer, Director, Chronic Care Policy Group, HCFA to Mr. Lewis Golinker, Esq., Director, Assistive Technology Law Center (May 4, 2001); *see* Tab 1.

Notably, the features and capabilities listed in the Coverage Reminder as precluding coverage all existed when the NCD was developed. Indeed, there is no question that CMS staff understood in 2001 when the NCD clarification was issued, and in 1999-2001, when the NCD for SGDs was being developed, that speech generation was not the “sole” feature of SGDs. For example, CMS staff and the contractor medical directors were provided product literature from the major SGD manufacturers, several in-person demonstrations of devices, and the opportunity to tour the exhibits and speak with SGD users, and SGD manufacturer staff at the 2000 conference of the International Society for Augmentative and Alternative Communication, which was held in Washington, D.C.

Not only do the Coverage Reminder requirements overlook the value to speech-generation of features such as wireless capability, but also they impose a standard prohibiting the device from incorporating *any* other components for the device. Importantly, the regulatory definition of DME is that the device must be “primarily and customarily used to serve a medical purpose.”¹³ In other words, it need not be only used for a medical purpose. The Coverage Reminder therefore improperly forecloses coverage if any functionality that is viewed as beyond speech-generation can be made available by “unlocking” hardware or software.

At the same demonstration referenced above, CMS staff and contractor medical directors were provided with information about how SGDs may include an infrared transmitter which, if additional equipment was purchased, enable patients to use an SGD to control a telephone, computer, lights, windows, door locks and electronic appliances; and included alarm features, calculator, calendar, clock, and text storage features enabling creation of lists or memos. Computer access (also with additionally-purchased equipment) was explained as a means to back-up the content in case of device malfunction and it allowed computers to be used to program new messages that could be transferred to the SGD at a time the device was not being used (e.g., when the patient was sleeping).

It is also notable that CMS staff and the contractor medical directors were also informed in 2001 that the modification of computer- and PDA-based devices to become functionally “dedicated” SGDs was not permanent and devices could be “unlocked” when ownership of the SGD transferred to the Medicare recipient. Their response, consistent with CMS policy then and today, is that Medicare does not prohibit a recipient-owner of DME from modifying that equipment at his or her own expense.

Finally, although the SGD manufacturers uniformly deliver “dedicated” devices and will not unlock devices until after ownership transfers to the Medicare beneficiary, the manufacturers’ experience has been that unlocking, a procedure over which they have exclusive control, is a “capability” sought by approximately ten (10) percent of Medicare-purchased SGDs. The Medicare beneficiaries who elect to have their devices unlocked represent a very small number of conditions, specifically, people with ALS or other impairments that do not affect cognitive function. Perhaps more significantly, now that these items are classified as “capped rental,” for a person with ALS, the most likely Medicare patient to seek unlocking, the

¹³ 42 C.F.R. § 414.202.

progression of the condition may render moot any possible benefit of this procedure more than a year after SGD need has been identified and use has begun.

Conclusion

Based on the foregoing, the Coverage Reminder is both inconsistent with longstanding policy and simply presents a bad policy. Effective September 1, 2014, the Coverage Reminder requires all manufacturers to submit new coding verification requests or be removed from the PDAC's Medicare Classification List. This would mean that a submission must be made to the PDAC contractor by June 1, 2014, underscoring the urgent timing here. We urge, therefore, your immediate review of this matter and that the Coverage Reminder be rescinded before June 1st. We will be contacting you in the next couple of days to discuss this matter and our raised concerns.

We look forward to discussing this letter with you and your team in greater detail. If you have any questions at this time, I can be reached at (202) 637-2169.

Sincerely,



Stuart S. Kurlander
of LATHAM & WATKINS LLP

Enclosure

cc: Joel Kaiser, CMS
Dr. Paul Hughes, NHIC, Corp.
Dr. Robert Hoover, CGS Administrators, LLC
Dr. Stacey Brennan, National Government Services, Inc.
Dr. Eileen Moynihan, Noridian Healthcare Solutions, LLC
Dr. Robert Szczys, Noridian Healthcare Solutions, LLC
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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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