COMMENTS TO REGIONAL MEDICAL REVIEW POLICY ON "SPEECH GENERATING DEVICES"

Exhibit A

Specific Comments to the RMRP

Table of Contents

A. Comments Related To HCPCS Coding

i. Device Codes

Concern: Coverage of Personal Digital Assistant (PDA) based AAC devices require consideration of a new code.

Proposed Solution: To the extent Personal Digital Assistant (PDA) based AAC devices will be covered for Medicare reimbursement, comments were received regarding the need issue a new code that will address these devices.

PDAs represent a operating platform for AAC devices. However, the characteristics of these devices do not match any of the existing codes. They have some characteristics of Kxxx3 devices, and some characteristics of Kxxx4 devices. Specifically, the PDA-based devices generate synthesized speech, and some offer both synthesized and digitized speech output. They also offer multiple methods of message assembly (spelling, picto-grams, etc.). However, not all of the PDA based devices will support indirect selection methods, which is a characteristic of the Kxxx3 code, and none will support the full range of alternate access devices, as compared to the Kxxx4 devices.

Some of the PDA based devices will support switches for scanning, but because of the small size of their display, they are unlikely to be viewed as a device for which indirect selection methods will be considered as an initial use of the device. Rather, their ability to support switches and their use as a scanning based device is likely be of benefit for individuals whose initial use was physical contact direct selection, but whose abilities changed, necessitating the use of scanning later. In this way, these devices are similar to the Light Writer, which as a Kxxx3 device, requires message assembly by physical contact direct selection, but which offers additional hardware to support switch-based scanning.

Thus, these devices do not fit precisely within either the Kxxx3 or Kxxx4 code.

For this reason, to the extent Medicare coverage will be extended to these devices, it will be necessary to consider an additional HCPCS code.

B. Comments Related to the RMRP Definitions

i. "Speech Generating Devices"

Concern: The reference to "speech impairment" in the definition of Speech Generating Devices may cause confusion as to the range of communication impairments for which AAC devices may be provided.

Proposed Solution: Substitute "speech, language and voice" impairment, or "severe expressive communication impairment" for the phrase "speech impairment."

"Speech generating device" is defined in the RMRP as "speech aids that provide individuals with **severe speech impairment** the ability to meet their functional speaking needs." (Page 1, Definitions).

The comments expressed concern that Medicare AAC device coverage may be mis-construed as being *limited* to individuals with speech impairments. Such an interpretation would be in error because AAC devices are of benefit to individuals with a wider range of impairments than those related to speech production. The *Formal Request* and the supplemental materials prepared for HCFA in response to the web-site comments identified communication impairments

in addition to "speech impairments" for which AAC devices are recognized as appropriate treatment in the professional literature and accepted in professional practice.

For this reason, it is proposed that the terminology used in the definition be clarified by replacing "severe speech impairment" with either "speech, language, and voice impairments," or "severe expressive communication impairments." This will lead the definition to state:

> Speech generating devices (SGDs) are defined as speech aids that provide individuals with severe speech, language, and voice impairments the ability to meet their functional speaking needs.
>
> Or
>
> Speech generating devices (SDS) are defined as speech aids that provide individuals with severe speech expressive communication impairments the ability to meet their functional speaking needs.

[deleted items ~~struck through~~; new text underlined].

Concern: The phrase "speech generating devices" is unfamiliar to the professional community and to other payers.

Proposed Solution: Three alternatives have been proposed: make no name change; or replace "speech generating devices" with the phrase "augmentative communication devices" or "voice output communication aids."

Many comments questioned why any name change for AAC devices was proposed in the RMRP, and more specifically, that "speech-generating devices" is a phrase unfamiliar to both the professional community as well as other payers who may look to Medicare for guidance regarding coverage of AAC devices.

Three proposals were offered in response to these concerns: one is to leave the device category name as Augmentative and Alternative Communication (AAC) devices. Or, to the extent a name change is deemed necessary, two alternatives were offered: "Augmentative Communication Devices ("AAC devices" or "ACDs") and "Voice Output Communication Aids"or ("VOCAs").

Augmentative and Alternative Communication devices (AAC devices) and its synonym. Augmentative Communication Devices (AAC devices or ACDs) represent terms of art in the vocabulary of health care services. These terms, as explained in the *Formal Request*, evolved of the past 40 years to represent the devices that treat severe speech, language, and voice communication impairments. The phrase AAC devices and the field of AAC intervention has come to be recognized by health care practitioners, as well as benefits program administrators as representing a particular class of services and devices, which serve a particular purpose related to communication, not sensory or other impairments. Indeed, even the Medicare program recognized these devices as "augmentative communication devices," for that was the reference used in National Coverage Decision 60-9, which the RMRP will replace.

Because these phrases and their meaning have been in such long-standing usage, some commenters reported that no change should be contemplated absent compelling need. Moreover, to the extent the presumption against a name change can be overcome, the commenters reported that the alternate name should be one with which AAC professionals and payers are familiar as compared to a novel phrase.

In general usage, there is no meaningful difference between "Augmentative and Alternative Communication Devices, and "Alternative Communication Devices." As noted above, the scope of devices that "fit" within the meaning of these terms is well understood. Moreover, based on the plain language of the definition of this term, the scope of devices that might be covered can be readily controlled.

For example, concern that an expansion of the device category to cover "alternative communication devices" such as a "braille typewriter" is without foundation. The plain meaning of the words used in the definition of these devices makes clear that an individual must have a "speech, language, or voice" impairment, or a "severe expressive communication impairment." But neither visual impairment nor blindness, which may give rise to a need for communication in braille, are speech, language, voice or expressive communication impairments. Also, a device such as a braille typewriter is a *reading* or *writing aid*, not a "speech aid," and it is used to meet a person's *reading* or *writing* needs, not speaking needs.

Neither a braille typewriter nor a standard typewriter are AAC devices, just as they are not SGDs.

However, to the extent additional concerns exist regarding the unpredictable expansion of the device category through coverage claims for "alternative communication" devices, one proposal is to eliminate those two words, and to allow the device category to follow its most common spoken name: Augmentative Communication Devices. Use of this phrase will prevent claims for coverage by "alternative communication" devices, it will have clear meaning to the professional community and to other payers, and, as noted above, this is precisely the wording of National Coverage Decision 60-9.

A second group of comments addressed how to select a "different" name for this device category. The suggestion made was to select a term that will be easily recognized by professionals and payers, and to adopt a novel phrase only as a last resort. By following this course, confusion can be minimized.

Following that logic, commenters suggested that the DMERCs consider renaming the device category as "voice output communication aids," or VOCAs. This is a phrase that is used commonly in the AAC intervention professional literature, and it is well understood by the AAC clinical professional community.

VOCAs are synonymous in AAC intervention jargon with "high tech(nology) AAC techniques" and they are contrasted with non-voice output aids which are often described as "low-tech" or "no-tech" AAC solutions. The latter category includes alphabet boards, communication books and other similar communication tools that permit expressive communication but which do not generate speech. In the *Formal Request*, the need for a speech output communication aid was identified as one of the nine key clinical indicators that SLPs must consider when conducting a comprehensive assessment. *See Formal Request* at pp. 39-40 (Select AAC Treatment Options; and Table 4, item 3).

By contrast, there is no reference to "speech generating devices" in the professional literature and none in any other benefits program. For this reason, use of the phrase "voice output communication aid" is a much preferred choice than "speech generating devices."

It is recommended, therefore, that both the device name, and all internal references to "speech-generating devices" be replaced with one of the phrases described above.

ii. Speech-Language Pathologists

Concern: The definition of "speech-language pathologists" is not correct.

Proposed Solution: The American Speech-Language-Hearing Association has proposed a corrected definition to replace the definition in the RMRP.

The RMRP defines speech-language pathologists as follows:

> Speech-language pathologists (SLPs) are licensed allied health professionals trained in the diagnosis and treatment of speech and language disorders. The SLP must hold a Certificate of Clinical Competence (CCC) from the American Speech and Hearing Association.

The American Speech-Language-Hearing Association had four comments in regard to this definition. First, ASHA stated that the word "allied" should be deleted from the definition because SLPs are "autonomous practitioners under state law and the ASHA certification program." A second comment is that SLPs hold either master's or doctoral degrees and this should be added to the definition. ASHA's third comment is to recommend a clarification to the Certificate of Clinical Competence, that it expressly refer to speech-language pathology, because audiologists also receive this ASHA certificate. Finally, ASHA noted that the name of the organization should be corrected to American Speech-Language-Hearing Association.

These comments lead to the proposal that the definition of Speech-language pathologist be revised as follows:

> Speech-language pathologists (SLPs) are licensed allied health professionals educated at the graduate level in the study of human communication, its development, and its disorders, trained in the diagnosis and treatment of speech ~~and language disorders.~~ The SLP must hold a Certificate of Clinical Competence (CCC) in speech-language pathology from the American Speech-Language-Hearing Association ~~American Speech and Hearing Association~~.

[deleted items struck through; new text underlined].

iii. Synthesized Speech

Concern: Use of the phrase "using algorithms representing linguistic rules" in the definition of synthesized speech, although taken verbatim from the *Formal Request*, at p. 72, is not the only way in which speech-synthesis software is designed.

Proposed Solution: Eliminate this phrase from the definition.

A comment was received that while *some* speech-synthesis programs "[use] algorithms representing linguistic rules," this is not the only way in which speech synthesis can be achieved. Thus, the definition appears to express a preference if not an express limitation on the type of speech synthesis technology that will be covered by Medicare.

The *Formal Request* did not intend to describe an exclusive or even a preferred way in which speech-synthesis technology operates, but instead, it sought to explain speech synthesis for individuals who are not familiar with the operating characteristics of AAC devices. The manner in which speech synthesis occurs is not an important characteristic related to whether a device or software program should be covered by Medicare, and the removal of this phrase from the definition does not change its meaning.

Therefore, it is recommended that the definition of speech synthesis be changed as follows:

> Synthesized speech (Kxxx3, Kxxx4), unlike the pre-recorded messages of digitized speech, is a technology that translates a user's input into device-generated speech, ~~using algorithms representing linguistic rules.~~ Users of synthesized speech SGDs are not limited to pre-recorded messages but rather can independently create messages as their communication needs dictate.

[inserted items underlined; deleted words ~~struck through~~]

iv. Kxxx4 Devices

Concern: The definition of Kxxx4 devices appears to have a grammatical error.

Proposed Solution: Add the phrase "the capability for" message selection, just as it appears in the description of access methods.

A comment noted the inclusion of the phrase "the capability to" with regard to multiple methods of access, but its omission in the preceding text, regarding multiple methods of message formulation. This was noted as a grammatical issue, not a substantive one.

Concern: The definition's list of specialized access devices omits reference to "switches" the most common means by which alternative access is achieved. This omission was noted as a source of confusion by many commenters who questioned whether switches covered under this policy.

Proposed Solution: It was recommended that the word "switches" be inserted at the beginning of the list of specialized access devices.

If these changes are made, the definition of the devices in the Kxxx4 code will be amended to be:

> Kxxx4 devices permit the user multiple methods of message formulation and multiple methods of device access. Multiple methods of message formulation must include the capability for message selection by two or more of the following methods: letters, words, pictures or symbols. Multiple methods of access must include the capability to access the device by two or more of the following: direct physical contact with a keyboard or touch screen, indirect selection techniques with a specialized access device such as one or more switches, a joystick, head mouse, optical head pointer, light pointer, infrared pointer, scanning device, or Morse Code.

[inserted items underlined]

v. Accessories

Concern: Although the definition of accessories includes a non-exclusive list of items ("include but are not limited to") commenters were concerned about the omission of the term "switches" to the items listed in the definition as examples. This was viewed as a more well recognized term than "SGD scanning devices."

Proposed Solution: Amend the definition by adding the term "switches" to the examples listed.

Concern: Another commenter noted that "wheelchair integration devices" were not listed among the examples in the definition, and that its omission may cause confusion whether these devices will be covered as accessories.

Proposed Solution: Amend the definition by adding the term "wheelchair integration devices" to the examples listed.

The RMRP definition of accessories for speech generating devices provides a non-exclusive list of items ("include but are not limited to"), for which the comments have been positive. This approach to accessories coverage is both necessary, due to the exceedingly broad range of these items, and appropriate, because new items are being developed on a continuing basis.

Wheelchair integration devices are accessories that will enable an individual whose AAC device is mounted on a power wheelchair to use the same control mechanism for the wheelchair and for the AAC device. This may be a joy-stick, head-rest control, or other control device. Wheelchair integration accessories allow the user to switch between wheelchair control functions and AAC device functions. By allowing these individuals to use a common control mechanism, their ability to produce messages will be improved.

It is recommended, therefore, that the definition of accessories be revised to state:

> Accessories for speech generating devices, (Kxxx7) 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, switches, optical head pointers, joysticks, wheelchair integration devices, and SGD scanning devices.

[new text underlined]

C. Comments Related to Coverage & Payment Rules

i. SLP Evaluation Requirements

Concern: Commenters noted that inconsistent terminology is used in this section to describe the nature of the impairments being evaluated. Although the different terms used (language, speech) may be intended as synonyms, confusion may result because these terms have distinct meanings to professionals.

Proposed Solution: Substitute the phrase "speech, language and voice abilities" for "language abilities" in Paragraph 1; substitute "communication" for "speech" in Paragraphs 2 and 5.

The reaction of those who reviewed this section of the RMRP has been exceedingly positive. By not requiring specific evaluation procedures to be utilized or requiring specific findings to be made, the RMRP is placing great trust in the speech language pathologists who will be conducting AAC device needs evaluations. The RMRP, therefore, is seen as presenting both an opportunity and obligation. It provides an opportunity for the speech language pathologists to use their professional skill and judgment in the evaluation of AAC device need. At the same time, SLPs recognize they have a responsibility to ensure that their evaluations are complete, their conclusions and recommendations well justified, and that their reports clearly document the evaluation and decision making process.

In response to the RMRP, an "implementation team" of AAC professionals was created at the November 2000 annual conference of the American Speech-Language-Hearing Association

(ASHA). The purpose of this group will be to develop a detailed template for SLPs to use for evaluation of AAC device needs, and to develop a reporting outline, so that AAC device recommendations are appropriately documented. The work products of the implementation team will be presented to you for your review. Thereafter, it will be posted at the web-site of the AAC Rehabilitation Engineering Research Center (AAC-RERC), whose members include many of the AAC professionals who helped write the *Formal Request*. [www.aac-rerc.com]. In addition, the implementation team will work with ASHA to develop training programs related to conducting complete evaluations and preparing complete reports, for speech-language pathologists in pre-professional and in continuing professional education training programs. The goal of these efforts will be to increase the overall level of skill of all SLPs, and to ensure that those SLPs who are undertaking AAC needs evaluations have all the proper tools necessary to meet Medicare's expectations and requirements.

Specific comments to the evaluation outline addressed the RMRP's use of terminology to describe communication impairment. These comments were consistent with those made in regard to the reference to "severe speech impairment" in the definition of speech generating devices, discussed above, *i.e.*, the terms used in the RMRP do not describe the full range of communication impairments being described. This issue arises in the evaluation guidelines in three places: ¶ 1:"language abilities;" ¶ 2:"expressive speech disability;" and ¶ 5:"speech disability."

The commenters recommended that consistent terminology be used throughout the RMRP. They recommended the following modifications to the RMRP:

> 1. Prior to the delivery of the SGD, the patient has had a formal evaluation of their cognitive and speech, language and voice ~~language~~ abilities by a speech-language pathologist (SLP). The formal, written evaluation must include, at a minimum, the following elements:
>
> 2. The patient's medical condition is one resulting in a severe expressive communication speech disability;
>
> 5. The patient's communication speech disability will benefit from the device ordered;

[inserted items underlined; deleted words ~~struck through~~]

ii. Comments Related to the "Dedicated Device" Limitation

The RMRP states that certain AAC devices will not be covered by Medicare. The specific text states:

> 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).

This sentence has generated the most comments and concerns. This sentence also is the subject of the only objections raised in regard to the RMRP. Stated below is the consensus of these comments, concerns, and objections.

The effect of this sentence, if implemented, will be to limit the range of device choices that can be selected by the speech-language pathologist and treating doctor. By doing so, for many individuals who have been identified as having AAC device needs, these clinical evaluation and treatment professionals will not be able to recommend the most appropriate device or most

cost-effective device to meet the individuals' needs. This limitation is neither necessary nor appropriate.

However, on November 30, HCFA issued National Coverage Decision 60-23, which constitutes the formal replacement of the former AAC device National Coverage Decision, # 60-9. This guidance both incorporates the "dedicated device" limitation and provides a further description of its intended meaning.

Because National Coverage Decisions are binding on the DMERCs, comments related to the dedicated device limitation are not re-stated here, but will be directed to HCFA staff.

D. Coding Guidelines

i. Items Included in the Kxxx1-Kxxx4 Codes

Concern: Comments were received regarding use of the term "interfaces" in this definition. It is not clear what this term means.

8**Proposed Solution:** Three solutions were proposed: delete this term, replace it with a synonym that is more well recognized by the professional community, or provide an explanation of what it is intended to cover.

Commenters noted that although the other items listed in this definition are readily identifiable and are typically included in the price of the device, "interfaces" is not a term commonly used in AAC device product delivery. As such, it is a source of confusion as to what it is intended to include. Commenters were concerned that "interfaces" may be interpreted to include alternative access devices. These items are not included in the price of the device, but are separately billed because of the wide range of products and product combinations that may be needed by individual users.

ii. Accessories

Concern: The RMRP description of the items that fall within the scope of the Kxxx7 code mentions access devices but once again fails to make reference to "switches." A second item identified as not listed here is "wheelchair integration accessories."

Proposed Solution: It is recommended that the wording in the RMRP be consistent and that both of these items be expressly listed here.

iii. Coding Information

Concern: The RMRP does not make clear that the "coding verification" procedure is not required before Medicare reimbursement can commence.

Proposed Solution: A sentence should be added to the text that clarifies that this procedure is not required.

A comment was received that the RMRP should expressly inform manufacturers and providers of AAC devices, software and accessories that there is no requirement that a coding verification by the SADMERC must be sought in order for an item of durable medical equipment, or a prosthetic or orthotic device to be reimbursed under the Medicare program. It was recommended that the following text be added to the RMRP:

> A supplier wanting to know which code to use to describe a particular product should contact the Statistical Analysis DME Regional Carrier (SADMERC).

However, there is no requirement that a coding verification by the SADMERC must be sought in order for an item of durable medical equipment, or a prosthetic or orthotic device to be reimbursed under the Medicare program.

[added text underlined]

E. Documentation

i. Billing for Software & Accessories

Concern: The RMRP does not make clear whether the specific brand name and model number is a required part of the documentation for all items, including AAC devices, as compared to just software and accessories.

Proposed Solution: Revise the RMRP text to state that billing for all codes for AAC devices and accessories require the specific brand name and model number.

The revised text of this paragraph will state:

When billing codes Kxxx1 ~~Kxxx5~~-Kxxx7, the claim must include documentation indicating the brand name and model name/number of the item provided. This information must be included with the claim if submitted hard copy or transcribed into the HA0 record of an electronic claim.

[added text underlined; deleted text struck through]

SUMMARY OF PROPOSED CHANGES TO DRAFT RMRP

Exhibit B

KEY: Throughout this Exhibit, new text is underlined and deleted text has been ~~struck through~~.

SUBJECT: AUGMENTATIVE COMMUNICATION DEVICES

or

VOICE OUTPUT COMMUNICATION AIDS

~~SPEECH-GENERATING DEVICES~~[1]

HCPCS CODES:

The appearance of a code in this section does not necessarily indicate coverage.

Kxxx1 – Augmentative communication device or Voice output communication aid ~~Speech generating device~~, digitized speech, using pre-recorded messages, less than or equal to 8 minutes recording time

Kxxx2 - Augmentative communication device or Voice output communication aid ~~Speech generating device~~, digitized speech, using pre-recorded messages, greater than 8 minutes recording time

Kxxx3 - Augmentative communication device or Voice output communication aid ~~Speech generating device~~, synthesized speech, requiring message formulation by spelling and access by physical contact with the device

Kxxx4 - Augmentative communication device or Voice output communication aid ~~Speech generating device~~, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access

Kxxx5 – Augmentative communication device or Voice output communication aid ~~Speech generating device~~ software program, for personal computer or personal digital assistant

Kxxx6 – Accessory for Augmentative communication device or Voice output communication aid ~~Speech generating device~~, mounting system

Kxxx7 – Accessory for Augmentative communication device or Voice output communication aid ~~Speech generating device~~, not otherwise classified.

---

[1] *See* Comments, at pages 1-3

HCPCS MODIFIER:

ZX- Specific requirements found in the Documentation section of the medical policy have been met and evidence of this is available in the supplier's records

BENEFIT CATEGORY: Durable Medical Equipment

REFERENCE:

DEFINITIONS:

Augmentative communication devices or Voice output communication aids ~~Speech generating devices (SGDs)~~ are defined as speech aids that provide individuals with ~~severe~~ speech, language, and voice impairment the ability to meet their functional speaking needs.

Or

Augmentative communication device or Voice output communication aid ~~Speech generating devices, (SGDs)~~ are defined as speech aids that provide individuals with severe communication ~~speech~~ impairment the ability to meet their functional speaking needs.[2]

Speech-language pathologists (SLPs) are ~~licensed allied~~ health professionals educated at the graduate level in the study of human communication, its development, and its disorders. ~~trained in the diagnosis and treatment of speech and language disorders.~~ The SLP must hold a Certificate of Clinical Competence (CCC) in speech-language pathology from the American Speech-Language-Hearing Association ~~American Speech and Hearing Association.~~[3]

Digitized speech (Kxxx1, Kxxx2), sometimes referred to as devices with "whole message" speech output, utilize words or phrases that have been recorded by an individual other than the AAC device or VOCA ~~SGD~~ user for playback upon command of the AAC device or VOCA ~~SGD~~ user.

Synthesized speech (Kxxx3, Kxxx4), unlike the pre-recorded messages of digitized speech, is a technology that translates a user's input into device-generated speech ~~using algorithms representing linguistic rules.~~ [4] Users of synthesized speech AAC devices or VOCAs ~~SGDs~~ are not limited to pre-recorded messages but rather can independently create messages as their communication needs dictate.

---

[2] *See* Comments, at pages 1-3.

[3] *See* Comments, at page 4.

[4] *See* Comments, at pages 4-5.

Kxxx3 devices require that the user make physical contact with a keyboard, touch screen or other display containing letters.

Kxxx4 devices permit the user multiple methods of message formulation and multiple methods of device access. Multiple methods of message formulation must include the capability for message selection by two or more of the following methods: letters, words, pictures or symbols. Multiple methods of access must include the capability to access the device by two or more of the following: direct physical contact with a keyboard or touch screen, indirect selection techniques with a specialized access device such as one or more switches, a joystick, head mouse, optical head pointer, light pointer, infrared pointer, scanning device, or Morse Code.[5]

Speech generating software programs (Kxxx5) enable a laptop computer, desktop computer or personal digital assistant (PDA) to function as an AAC device or VOCA ~~SGD~~. Within this policy, the term AAC device or VOCA ~~SGD~~ also describes these speech generating software programs.

Mounting systems (Kxxx6) are devices necessary to place the AAC device or VOCA ~~SGD device,~~ switches and other access devices within the reach of the patient.

Accessories for speech generating devices (Kxxx7) 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, switches, optical head pointers, joysticks, wheelchair integration devices, and AAC or VOCA ~~SGD~~ scanning devices.[6]

COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must: 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this regional medical review policy, "reasonable and necessary" is defined by the following coverage and payment rules.

An augmentative communication device or A voice output communication aid ~~speech-generating device~~ (Kxxx1 – Kxxx5) is covered when all of the following criteria (1-7) are met:

1. Prior to the delivery of the AAC device or VOCA, ~~SGD~~, the patient has had a formal evaluation of their cognitive and speech, language and voice ~~language~~ abilities by a speech-language pathologist (SLP). The formal, written evaluation must include, at a minimum, the

---

[5] *See* Comments, at page 5-6.

[6] *See* Comments, at page 6-7.

following elements:

a) current communication impairment, including the type, severity, language skills, cognitive ability, and anticipated course of the impairment;

b) an assessment of whether the individual's daily communication needs could be met using other natural modes of communication;

c) a description of the functional communication goals expected to be achieved and treatment options;

d) rationale for selection of a specific device and any accessories;

e) treatment plan that includes a training schedule for the selected device;

f) demonstration that the patient possesses the cognitive and physical abilities to effectively use the selected device and any accessories to communicate;

g) for a subsequent upgrade to a previously issued AAC device or VOCA ~~SGD~~, information regarding the functional benefit to the patient of the upgrade compared to the initially provided AAC device or VOCA ~~SGD~~; and,

2. The patient's medical condition is one resulting in a severe expressive communication ~~speech~~ disability; and,

3. The patient's speaking needs cannot be met using natural communication methods; and,

4. Other forms of treatment have been considered and ruled out; and,

5. The patient's communication ~~speech~~ disability will benefit from the device ordered; and,

6. A copy of the SLP's written evaluation and recommendation have been forwarded to the patient's treating physician prior to ordering the device; and,

7. The SLP performing the patient evaluation may not be an employee of or have a financial relationship with the supplier of the AAC device or VOCA ~~SGD~~.[7]

If one or more of the AAC device or VOCA ~~SGD~~ coverage criteria 1-7 is not met, the AAC device or VOCA ~~SGD~~ will be denied as not medically necessary.

Codes Kxxx1 – Kxxx4 and code Kxxx5 perform the same essential function – speech generation. Therefore, claims for more than one AAC device or VOCA ~~SGD~~ will be denied as not medically necessary.

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]

Software (Kxxx5) that enables a laptop computer, desktop computer or PDA to function as an AAC device or VOCA ~~SGD~~ is covered as an AAC device or VOCA ~~SGD~~; however, installation of the program or technical support are not separately reimbursable.

---

[7] *See* Comments, at pages 6-7.

[8] *See* Comments, at pages 7-8.

Accessories

Accessories (Kxxx7) for Kxxx1 – Kxxx4 are covered if the basic coverage criteria (1-7) for the base device are met and the medical necessity for each accessory is clearly documented in the formal evaluation by the SLP.

CODING GUIDELINES:

Code E1900 (Synthesized speech augmentative communication device with dynamic display), effective for dates of service on or after the effective date of this policy, is no longer valid for submission to the DMERC.

Codes Kxxx1 and Kxxx2 must be used to code devices that generate only digitized speech output.

Codes Kxxx3 and Kxxx4 must be used to code devices that generate synthesized speech. Devices that have the capability to generate both digitized and synthesized speech must be coded Kxxx3 or Kxxx4, depending on the method of synthesized speech formulation and device access.

Codes Kxxx1 – Kxxx4 include the device, any applicable software, ~~interfaces~~, batteries, and battery charging components. These items may not be billed separately.[9]

Code Kxxx5 is used to code for a speech generating software program that enables a laptop computer, desktop computer or personal digital assistant (PDA) to function as an AAC device or VOCA ~~SGD~~. The allowance for code Kxxx5 includes the speech generating software program only. Installation of the program or technical support must not be billed separately. Code Kxxx5 must not be used to code software included with the initial provision of the AAC device or VOCA ~~SGD~~ (Kxxx1 – Kxxx4) since the software cost is included in the reimbursement for those AAC device or VOCA ~~SGD~~ codes. In addition, code Kxxx5 must not be used to code software included with the initial provision of the access device (Kxxx7) since the software cost is included in the reimbursement for the access device.

Upgrades to Kxxx5 are subsequent versions of a speech generating software program that may include enhanced features or other improvements. Upgrades to Kxxx5 must be coded Kxxx5.

Mounting systems necessary to place the AAC device or VOCA ~~SGD~~ device, switches and other access devices within the reach of the patient must be coded Kxxx7.

Accessories to AAC devices or VOCAs ~~SGDs~~ such as access devices should be coded Kxxx7. There should be no separate billing of any software, interfaces, cables, adapters, interconnects, or switches necessary for the accessory to interface with the AAC device or VOCA ~~SGD~~ (Kxxx1 – Kxxx5).

---

[9] *See* Comments, at page 8.

Upgrades to Kxxx1 – Kxxx4 are subsequent versions of the device's software program or memory modules that may include enhanced features or other improvements. Upgrades to Kxxx1 – Kxxx4 must be coded Kxxx7.

A supplier wanting to know which code to use to describe a particular product should contact the Statistical Analysis DME Regional Carrier (SADMERC). However, there is no requirement that a coding verification by the SADMERC must be sought in order for an item of durable medical equipment, or a prosthetic or orthotic device to be reimbursed under the Medicare program.[10]

DOCUMENTATION:

For an item(s) to be considered for coverage and payment by Medicare, the information submitted by the supplier must be corroborated by documentation in the patient's medical records that Medicare coverage criteria have been met. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals, or test reports. This documentation must be available to the DMERC upon request.

An order for the AAC device or VOCA ~~SGD~~ and all accessories must be signed and dated by the treating physician and kept on file by the supplier. For codes Kxxx1 – Kxxx7, if all of the coverage criteria for these devices specified in the Coverage and Payment Rules section if the policy have been met and if the supplier has a copy of the required SLP evaluation, a ZX modifier should be added to the code. A ZX modifier must not be used if any of the requirements listed above are not met.

When billing codes Kxxx1 ~~Kxxx5~~-Kxxx7, the claim must include documentation indicating the brand name and model name/number of the item provided. This information must be included with the claim if submitted hard copy or transcribed into the HA0 record of an electronic claim.[11]

Refer to the Supplier Manual for more information on orders, medical records, and supplier documentation.

EFFECTIVE DATE:

Claims with dates of service on or after

---

[10] *See* Comments, at page 8.

[11] *See* Comments, at page 9.