Robert D. Hoover, Jr., MD
Medical Director
DMERC Region D

CIGNA HealthCare
Medicare Administration

Routing 795
2 Vantage Way
Nashville TN 37228
Telephone 615.782.4541
Facsimile 860.731-3965

October 24, 2000

Lewis Golinker, Esq.
Director, Assistive Technology Law Center
202 E. State Street, Suite 507
Ithaca, NY 14850

RE: Speech Generating Device Draft Policy

Dear Lew:

Thank you for offering to serve as the coordinator of comments from the AAC Coalition. Enclosed is the draft policy on Speech Generating Devices developed by the DMERC medical directors. Also, please note that I am sending a copy of the policy to each organization on the e-mail list you sent me a few weeks ago.

The comment period begins on October 24, 2000 and ends on December 19, 2000. If you disagree with any aspect of the policy, you should be very specific and if possible, offer an alternative indication, guidelines, etc. You should provide a clinical rationale for your position. If comments relate to medical necessity criteria, you should include references from standard textbooks and/or peer-reviewed journals. We would also encourage a written response if you agree with the policy.

When comments on this policy have been received, they will be reviewed and revisions to the policy will be considered. The revised policy will be published in future DMERC Regional Bulletins and Supplier Manual updates, allowing for adequate notice, prior to the policy's effective date.

Please submit your comments to each DMERC medical director by mail at the addresses below no later than December 19, 2000. Facsimile responses are not acceptable. Thank you for your assistance in our policy development process.

Cordially,

Paul Hughes, M.D.
Medical Director, DMERC Region A
HealthNow
60 E. Main Street
Nanticoke, PA 18634-1685

Paul Metzger, M.D.
Medical Director, DMERC Region C
Palmetto GBA
P.O. Box 100141, Mail Stop AG-250
Columbia, SC 29223

Adrian M. Oleck, M.D.
Medical Director, DMERC Region B
AdminaStar Federal
8115 Knue Road
Indianapolis, IN 46250

Robert D. Hoover, Jr., M.D.
Medical Director, DMERC Region D
CIGNA Healthcare–Medicare Administration
2 Vantage Way
Nashville, TN 37228

Lew,
Thanks for all your help.
Bob

Connecticut General Life Insurance Company
Part B & DME Contracted Carrier for

Health Care Financing Administration

SUBJECT: SPEECH-GENERATING DEVICES

HCPCS CODES:

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

Kxxx1 – Speech generating device, digitized speech, using pre-recorded messages, less than or equal to 8 minutes recording time
Kxxx2 - Speech generating device, digitized speech, using pre-recorded messages, greater than 8 minutes recording time
Kxxx3 - Speech generating device, synthesized speech, requiring message formulation by spelling and access by physical contact with the device
Kxxx4 - Speech generating device, synthesized speech, permitting multiple methods of message formulation and multiple methods of device access
Kxxx5 – Speech generating software program, for personal computer or personal digital assistant
Kxxx6 – Accessory for speech generating device, mounting system
Kxxx7 – Accessory for speech generating device, not otherwise classified.

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:

Speech generating devices (SGDs) are defined as speech aids that provide individuals with severe speech impairment the ability to meet their functional speaking needs.

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.

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 SGD user for playback upon command of the 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. Users of synthesized speech SGDs are not limited to pre-recorded messages but rather can independently create messages as their communication needs dictate.

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 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 a joystick, head mouse, optical head pointer, light pointer, infrared pointer, scanning device, or Morse Code.

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

Mounting systems (Kxxx6) are devices necessary to place the 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, optical head pointers, joysticks, and SGD scanning devices.

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.

A speech-generating device (Kxxx1 – Kxxx5) is covered when all of the following criteria (1-7) are met:

1. Prior to the delivery of the SGD, the patient has had a formal evaluation of their cognitive and language abilities by a speech-language pathologist (SLP). The formal, written evaluation must include, at a minimum, the 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 SGD, information regarding the functional benefit to the patient of the upgrade compared to the initially provided SGD; and,
2. The patient's medical condition is one resulting in a severe expressive 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 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 SGD.

If one or more of the SGD coverage criteria 1-7 is not met, the 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 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).

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

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.

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 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 SGD (Kxxx1 – Kxxx4) since the software cost is included in the reimbursement for those 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 SGD device, switches and other access devices within the reach of the patient must be coded Kxxx7.

Accessories to 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 SGD (Kxxx1 – Kxxx5).

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).

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 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 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.

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