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MEMORANDUM

TO: Madeline Ulrich, M.D.

FROM: Lewis Golinker

RE: Responses to HCFA Web-site Comments

Date: June 29, 2000

I write on behalf of the organizations that submitted the *Formal Request for National Coverage Decision for Augmentative and Alternative Communication Devices*, CAG-00055: the American Speech-Language-Hearing Association, Amyotrophic Lateral Sclerosis Association, Brain Injury Association, Center for Disability and Health, Communication Aid Manufacturers Association, Communication Independence for the Neurologically Impaired, International Society for Augmentative and Alternative Communication, National Association of Protection and Advocacy Systems, National Multiple Sclerosis Society, RESNA, Sunrise Medical, United Cerebral Palsy Associations, and United States Society for Augmentative and Alternative Communication.

Attached to this memorandum are our initial responses to the HCFA web-site posting on April 26 regarding the AAC device *Formal Request*. As Marcia Nusgart explained, these responses will be supplemented in the next few weeks with additional information specifically related to AAC device outcomes.

Please call or send me an e-mail message if you have questions about these responses or the documents attached at Tabs 1-5.

Thank you.

RESPONSE TO WEBSITE INQUIRIES ON AAC DEVICES

The information provided below supplements the *Formal Request for National Coverage Decision for Augmentative and Alternative Communication Devices*, CAG-00055, submitted on December 30, 1999. These responses address the topics identified below. As you requested, for each topic, the specific HCFA web-site paragraph has been re-stated, and then the response is provided. Topics discussed:

1. Identification of Patients, Evaluation Criteria, Outcome Studies
2. NICD Sponsored AAC Research
3. Physician Input
4. Severe Impairments; AAC Device Demand Estimate
5. Role of Physical Condition Diagnosis
6. Identification of Symptomatic or Functional Deficits
7. Cognitive Testing & Outcomes
8. Dysarthria Stages
9. Exclusions
10. Physician Testing
11. Training
12. Objective Measures Related to AAC Benefit

In addition, these responses are supplemented by materials annexed at Tabs 1 through 5.

1. Identification of Patients, Evaluation Criteria, Outcome Studies

HCFA's web-site stated:

> The material submitted in support of the request to cover AAC devices is suggestive of the utility of these devices of those with severe speech impairments, but did not offer sufficient medical evidence to permit identification of those patients; outcomes data supporting the beneficial long term effects of the devices; and criteria for evaluation of patients that would assure that they possess both the physical and cognitive ability to effectively use an AAC device.

Response:

Identification of Patients & Evaluation Criteria

AAC devices are a long-recognized form of speech-language pathology treatment for specific types of severe communication disability. Patients for whom AAC devices are necessary treatment are identified through a comprehensive assessment process conducted by speech-language pathologists (SLP).

The initial steps of this process involve the patient's treating physician. First, the treating physician must conclude (make a diagnosis that) the patient has a physical (neurological) condition that is associated with severe communication disability. Second, the treating physician must note that the patient is unable to use intelligible speech to engage in typical communication activities of daily life, and that the patient is motivated to engage in communication activities of daily life. When these two steps are completed, physician referral to a speech-language pathologist for comprehensive evaluation, including consideration of AAC devices, will be made.

The two steps described in the preceding paragraph have been added to the proposed AAC device coverage criteria that were submitted with the *Formal Request*. The revised coverage criteria are attached to these responses at Tab 1. These changes and the others, described below, reflect the comments posted at the HCFA web-site as well as comments we have received from personal contact with HCFA staff and from Michael Weinrich, M.D., Director of of the Center for Medical Rehabilitation Research, National Institute of Child Health & Human Development. We met with Dr. Weinrich on May 23, and spoke with him again on May 25.

A new coverage criterion # 1 has been inserted. It requires the patient's treating physician to identify the physical impairment diagnosis, and to certify that this condition is one that is associated with severe communication disability. This information must be included with an AAC device funding request.

New coverage criterion # 1 includes a non-exclusive list of 10 degenerative conditions and 7 stable conditions which are commonly associated with severe communication impairment. Because there are many other, exceedingly low incidence, but similar conditions that are associated with severe communication impairment, the list presented at Tab 1 is not intended to be exclusive. Coverage criterion # 1 states:

> 1. The individual has been evaluated by a physician and diagnosed with one of the following conditions, or another condition with which severe communication impairment is associated:
>
> Degenerative Diseases:
>
> Amyotrophic lateral sclerosis
> Other Motor Neuron Diseases (inclusive)
> Multiple sclerosis
> Huntington's disease
> Parkinson's disease
> Parkinson's Plus syndromes (inclusive)
> Cerebellar degenerative diseases (Inclusive)
> Friedreich's
> Spinocerebellar
> Wilson's disease & Other Genetic-metabolic conditions (Inclusive)
> Nervous System tumors (Selected)
> Myasthenia Gravis
>
> Stable Conditions (STABLE--RECOVERING)
>
> Brainstem stroke
> Locked-in-syndrome
> Cerebral Palsy
> Dystonia's (Inclusive)
> Guillian-Barre' syndrome
> Traumatic brain injury
> Cerebral Vascular Accident

A new coverage criterion # 2 also has been inserted. It requires the patient's treating physician to complete a checklist, which will be annexed to the proposed national coverage decision and which must be completed prior to making referral to an SLP for a comprehensive evaluation. Currently, the treating physician checklist is attached at Tab 2. Coverage criterion # 2 states:

2. The physician makes a referral for speech-language pathology and/or augmentative communication evaluation based on the existence of the signs and symptoms of communication impairment stated on the accompanying physician's checklist.

These two additional coverage criteria, which outline the role of the treating physician at the start of the SLP/AAC comprehensive assessment process, were suggested by Dr. Michael Weinrich.

Dr. Weinrich stated that the coverage criteria should state a comprehensive list of physical condition diagnoses, including both specifically named conditions and a general condition description to capture those exceedingly low incidence neurological conditions which nonetheless are associated with severe communication disability. Dr. Weinrich did not believe there were any physical conditions associated with severe communication disability that should, by themselves, be a barrier to allowing the rest of the process to move forward.

Dr. Weinrich also stated that the patient's treating physician is the appropriate medical professional to implement these first two steps of the process, which is incorporated into the revised coverage criteria. This conclusion contrasts with the repeated reference to a role for a "neurologist" in the HCFA web-site comments.

Dr. Weinrich also suggested the "physician checklist" which identifies the clinical facts the treating physician must observe before making referral for a comprehensive SLP/AAC evaluation. Medicare currently imposes no comparable data reporting requirement on physicians before making SLP referral. The physician checklist attached at Tab 2 was developed upon request made to the American Academy of Neurology. The work-group of physicians who developed this document believed it should be simple and not a barrier to allowing the assessment process to proceed. The new coverage criterion # 2 requires the completion by the treating doctor of this checklist and its inclusion as a required part of the Medicare funding request for an AAC device.

The third step in the patient identification process is the diagnosis of specific communication disability by the speech-language pathologist. The *Formal Request* identified the specific communication disabilities most commonly associated with AAC device need and use. These are dysarthria, apraxia and aphasia. The HCFA web-site comments suggest that AAC devices also may be appropriate for certain individuals with "aphonia."

Aphonia is a voice disorder characterized by the complete absence of vocal fold vibration (Crystal & Varley, 1998). Comprehensive speech-language pathology assessment related to aphonia follows the a parallel sequential process as is stated in the *Formal Request*, Section 3. The condition is diagnosed, individual functional communication goals are determined, and based on its nature and severity, treatment methodologies are considered. As with dysarthria, apraxia and aphasia, consideration is first given to SLP treatment techniques that will allow the individual to meet daily communication needs using natural communication methods. If those methods will not be sufficient, consideration is given to use of assistive devices. The most common assistive devices considered for individuals with aphonia are amplification devices and electronic speech aids, more commonly known as an artificial larynx. (Shames & Wiig, 1990). The latter devices, which include a device known as the Ultra Voice, have long been covered by Medicare as a prosthetic device, pursuant to National Coverage Decision 65-5.

Aphonia is not typically treated through use of AAC devices. For example, neither aphonia or its related condition dysphonia appear in the index for the standard treatise related to augmentative communication, Beukelman and Mirenda (1998). However, the American Speech-Language-Hearing Association reports that when neither natural communication, amplification devices or an

artificial larynx will be sufficient to allow the individual to meet daily communication needs, an AAC device will be considered. *See* Memo date June 27, 2000, attached at Tab 3.

For this reason, coverage criterion # 3 has been revised to include aphonia as one of the communication disabilities which supports further assessment of treatment options, including AAC devices. Coverage criterion # 3 now states:

> 3. The individual has been evaluated by a Speech-Language Pathologist and diagnosed with one of the following communication impairments: dysarthria, apraxia, aphasia or aphonia.

After the diagnosis of one of these communication disabilities is made, the *Formal Request*, Section 3 describes the next series of steps in the SLP assessment process. First, the severity of the individual's speech and language impairment, functional communication abilities and communication needs are considered, and the functional goals of SLP treatment are established. Consideration is then given to whether the individual's functional communication goals can be met by use of treatment that will improve natural communication methods. *Formal Request*, at 38-39.

When the SLP determines that an individual will not be able to meet daily communication needs using natural communication methods, the assessment process turns to consideration of AAC interventions. The HCFA web-site comments note that greater information is needed to explain the characteristics of the individuals for whom consideration will be given to AAC interventions. In response, a substantial revision has been made to coverage criterion # 4. New text explains how the severity of communication diagnoses are measured and the levels that are associated with individuals for whom consideration will be given to AAC interventions.

For dysarthria, the data and conclusions that are required are:

> a) For individuals with dysarthria, the SLP must conclude the severity of this condition is at Stages 4 or 5:
>
> > i) based on a finding that the individual received a score less than or equal to 90 % on the Sentence Intelligibility Test or the Sentence Test of the Assessment of Intelligibility of Dysarthric Speech; or
> >
> > ii) based on a finding that the individual has been found to be functioning at Level 1, Level 2, or Level 3 on the Motor Speech Functional Communication Measure (FCM) Section of the National Outcomes Measurement System; or
> >
> > iii) for individuals with Amyotrophic Lateral Sclerosis (ALS), based on a finding that the individual's rate of intelligible word production is less than or equal to 130 words per minute.

The Sentence Intelligibility Test and Sentence Test of Assessment of Intelligibility of Dysarthric Speech are the same instrument. The instructions, procedures, sentence pools and scoring procedures are the same. Their names are different to reflect the fact that the former is distributed by CD; the latter is the paper and pen version. The tests were authored by Kathryn Yorkston, Ph.D., and David Beukelman, Ph.D., two members of the professional work-group that wrote the *Formal Request*.

The severity measure of 90 % intelligibility reflects the level that is required for an individual to be understood in a telephone conversation as compared to face to face communication. This measure also reflects the level of intelligibility at which an individual will be understood by an unfamiliar listener or when the context of the communication is not known.

The Motor Speech Function Communication Measure is a 7 point scale ranging from least functional (Level 1) to most functional (Level 7). The scale contains references to the intensity and frequency of the cueing and compensatory strategies that are used by a patient with speech production impairments. Face validity was done on each FCM through peer review by 100-150 ASHA certified speech-language pathologists. Reliability testing was completed by randomly selecting and scoring various levels of each FCM with a minimum accuracy level of 80% needed for the FCM to be deemed reliable. American Speech-Language-Hearing Association. (1999). Rehabilitation Hospitals Annual Report 1999.

Because of the progressive nature of ALS, an additional measure has been included. It is generally accepted that consideration of AAC needs must begin as early as possible following the initial physical condition diagnosis of ALS. In addition, individuals with ALS often will attempt to compensate following onset of speech impairment by slowing the rate of speech production. Thus, for this population, the consideration of AAC interventions can begin upon the SLP's recognition that either intelligibility has been adversely affected, or word rate production has slowed.

The severity measure of 130 intelligible words per minute reflects a substantial rate reduction of speech production. This threshold for further assessment contrasts with the mean rate of typical speech production, which is 180 words per minute.

The inclusion of specific tests and measures in the coverage criteria was based on a suggestion by Dr. Weinrich. He agreed that individuals with severe dysarthria are an appropriate population for AAC device coverage, and specifically suggested that a test be included to measure intelligible words produced per measure of time. The tests identified above serve this purpose.

For apraxia, the data and conclusions that are required are:

> b) For individuals with a diagnosis of Apraxia, the SLP must conclude that the individual has a severe to profound apraxia.

The revision to coverage criterion # 4 also identifies a means by which this conclusion can be reached:

> To quantify apraxia severity, the SLP may use the expressive subtests and cutoff scores from the of the WAB or the BDAE (described below) or a standardized apraxia battery for adults (e.g., the Apraxia Battery for Adults (ABA-2, B.L. Dabul, Pro-ed publishers) which yields a severity rating based on normative data. The patient's severity rating must fall within the severe to profound range.

Dr. Weinrich agreed that coverage is appropriate for individuals with severe apraxia.

For aphasia, the data and conclusions that are required are:

> c) For individuals with a diagnosis of Aphasia, the SLP must conclude that the individual has an insignificant to a moderate impairment in language comprehension coupled with a severe impairment in expressive communication as

measured by either the Western Aphasia Battery (WAB) (1982), or the Boston Diagnostic Aphasia Examination (BDAE) (1983). The impairment in expressive communication may be due to a severe apraxia, a severe expressive language deficit, or a combination of these impairments.

i) *Language Comprehension Impairment*

Western Aphasia Battery: Administer Section II--*Auditory Verbal Comprehension*. The patient must receive an overall score of 4 or higher.

Boston Diagnostic Aphasia Examination: Administer Section II, *Auditory Comprehension*. The patient must receive an overall percentile ranking in the 30th percentile or greater.

ii) *Expressive Communication Impairment*

Western Aphasia Battery: Administer Section I, *Spontaneous Speech*, Scale B, *Fluency, Grammatical Competence and Paraphasias*. Patients with a severity score of five or below, are classified as having a severe expressive communication impairment.

Boston Diagnostic Aphasia Examination: Administer Section I, *Conversational and Expository Speech* and Section III, *Oral Expression*, Subtest A#2), *Verbal Agility*. Using the *Rating Profile of Speech Characteristics*, determine an overall severity rating (one: severe impairment to seven: insignificant impairment). An overall rating of four or lower indicates severe expressive communication impairment.

The HCFA web-site comments raised questions about the appropriateness of AAC device coverage for any individuals with aphasia. We reviewed this comment with Dr. Weinrich. His response, based on research he personally conducted related to the communication abilities of individuals with aphasia and his knowledge of the professional literature, is that AAC device coverage is appropriate for individuals with mild to moderate aphasia and severe apraxia. The appropriateness of coverage for such individuals was confirmed by David Beukelman, Ph.D., who conducted an informal survey of leading AAC clinicians who serve individuals with aphasia. *See* memo attached at Tab 4.

The coverage criteria were clarified to respond to Dr. Weinrich's suggestions. It has long been recognized that AAC interventions will address the functional gap that exists between an individual's ability to comprehend and to express language. (Shane, in Blackstone, Ph.D., Ed., 1986). The coverage criteria now state that an individual's comprehension ability must be impaired only to an "insignificant to moderate" degree, but that there is a substantial gap in the individual's ability to produce language, due to a "severe impairment in expressive communication."

Specific tests and measures have been included regarding these required findings. The Western Aphasia Battery (WAB) and Boston Diagnostic Aphasia Examination (BDAE) are two of the most commonly-used test instruments for individuals with aphasia. (Chapey, 1994). The specific subtests and scores that are included are those specifically relevant to language comprehension and expression.

For aphonia, the data and conclusions that are required are:

> d. For individuals with a diagnosis of Aphonia, the SLP must conclude that the individual is not able to use natural communication, amplification devices or an artificial larynx (electronic speech aid) to meet daily communication needs.

The rationale for including individuals with aphonia in the coverage criteria is described above.

For individuals who meet these severity measures of communication disability, the SLP evaluation next considers whether the individual requires a speech output communication device. This clinical decision is based on consideration of whether each individual's residual communication abilities and use of non-speech output AAC interventions will be sufficient to meet the individual's daily communication needs. This decision is based on the clinical facts and judgment of the SLP. Coverage criterion # 5 states:

> 5. The individual requires a speech output communication device to meet his/her functional communication goals.

Coverage criterion # 5, as it appeared in the *Formal Request*, is not changed.

Once it is determined that the individual requires a speech output communication device, a new coverage criterion # 6 is proposed. It states:

> 6. The individual possesses the cognitive, functional communication ability to use a speech output communication device to meet daily communication needs.
>
> a) For individuals diagnosed with traumatic brain injury, the individual has been determined to have cognitive functioning at Rancho Scale, Level VI-VIII (AAC intervention, late stages).

The HCFA web-site comments also make repeated reference to an individual's "cognitive" ability to use an AAC device. Consideration of cognitive, functional communication abilities always has been a part of the comprehensive SLP and AAC evaluation process. In the initial ASHA policy statement on "non-speech communication" the assessment process is described as including this consideration (ASHA, 1981), and it appears as well in the most recent ASHA policy statement on Augmentative and Alternative Communication. (ASHA, 1991). Consideration of cognitive, functional communication abilities also is incorporated in the "model policy" for Medicaid coverage of AAC devices (USSAAC, 1995).

The revised coverage criterion # 6 requires the SLP to make a specific finding related to the individual's cognitive functioning. With the exception of brain injury, no specific test or scales have been correlated with ability to learn to use a speech output communication device. Instead, SLPs consider cognitive functioning in the assessment process by examining the individual's responsiveness to a demonstration of the device; memory ability, including how to operate a device; ability to attend (remain on task); and ability to understand symbols. This consideration is made using a "diagnostic teaching" approach. The SLP will present the individual with the speech-output communication device(s) and demonstrate their use for communicating during the assessment session. During this dynamic assessment process, the SLP will observe the individual's ability to: attend to, and visually, tactually and/or auditorily search the communication display on the speech-output communication device to locate communication symbols (letters, pictures, icons) to construct his/her messages; plan, organize and execute his/her communicative initiations and responses using the AAC device; learn to operate the AAC device (e.g., how to

turn it on and off, how to care for the device such as charging batteries); and retain (remember) basic instructions following a break in the evaluation process.

For individuals with brain injury, Dr. Weinrich and David Beukelman, Ph.D. agreed that a set of measures known as the Rancho Scales, at Levels VI-VIII represent an appropriate test and measures to establish the cognitive abilities to use and benefit from AAC devices. The Rancho Scales are described in Ladtkow & Culp, 1992, which is included in the *Formal Request*, at Appendix II-B.

The *Formal Request*, Section 3, Part II discusses the remaining steps of the clinical assessment and decision making process which leads to identification of the appropriate category of AAC devices and the specific device and accessories that are necessary for each individual to meet his or her daily communication needs. These coverage criteria state:

> 7. The individual possesses the linguistic capability to formulate language (messages) independently.
>
> 8. The individual will produce messages most effectively and efficiently using spelling.
>
> 9. The individual will require an AAC device with extensive language storage capacity and rate enhancement features.
>
> 10. The individual will access the AAC device most effectively and efficiently by means of a physical contact direct selection technique, such as with a finger, other body part, stylus, hand held pointer, head stick or mouth stick.
>
> 11. The individual will access the AAC device most effectively and efficiently by means of an electronic accessory that permits direct selection.
>
> 12. The individual will access the AAC device most effectively and efficiently by means of an indirect selection technique (*e.g.*, scanning, Morse Code).

These coverage criteria have not been changed.

The HCFA web-site comments and subsequent conversations with HCFA staff touch upon an individual's physical ability to use an AAC device. Physical access of an AAC device is discussed in the *Formal Request*, in Sections 3 and 5 and are the subject of coverage criteria # 8 - 12.

There are 3 access methods: physical contact direct selection; direct selection by electronic aid or accessory; and indirect selection, more commonly called "scanning."

Physical contact direct selection involves routine actions that we all engage in regularly: e.g., using our fingers to type on a keyboard or using a pencil eraser to punch in a number on a touch-tone telephone. Both fingers and pointers are commonly used by people who use AAC devices. Physical contact direct selection is the most common AAC device access method. (LaFontaine & DeRuyter 1987; Slesaransky-Poe (unpubl. 1997). The other two access methods are considered for individuals who lack the ability to effectively and efficiently access an AAC device by physical contact direct selection. These aided access methods are considered in sequence. First, if an individual can make fine and accurate movements with his or her head, a variety of light-emitting devices are available which can activate specific "cells" on the AAC device. Other devices allow

an individual to use his or her head to simulate the actions of a computer mouse, and thereby activate cells on the device.

Or, if physical contact direct selection or direct selection by electronic aid is not an efficient and effective means to operate the AAC device, switch based access is considered. There is a very broad range of switches available to respond to almost any controllable, *i.e.*, volitional muscle movement by the individual. At the extreme end of this scale are eye-gaze based aids for individuals who have AAC needs as well as locked-in-syndrome, or ALS.

HCFA staff had the personal opportunity to handle and observe representative AAC devices from all 3 proposed AAC device categories on July 16, 1999 and February 24, 2000. All 3 types of access: physical contact direct selection; direct selection by electronic accessory; and switch-based scanning were demonstrated and made available to staff during these in-service trainings. In addition, HCFA staff has ready access to observe and speak with an AAC device user, Bob Williams, the Deputy Assistant Secretary for Disability, Aging and Long Term Planning. He uses a Liberator, a Category 3 AAC device, as well as a letter-board, which he accesses by physical contact direct selection (his finger).

HCFA staff, as members of the general public, also have had opportunities to see and/or read about Stephen Hawking, the physicist, who uses a Freedom 2000, a Category 3 AAC device. He accesses his device by a switch. Most recently, on June 25, the New York *Times* printed an article about an individual with ALS who uses and AAC device that she activates by a switch controlled by moving her lip/cheek/jaw.

Also, during the past year, *i.e.*, since HCFA announced its willingness to review the AAC NCD, CAG staff, notably Arnold Gibson, communicated directly with an AAC device user: Kim Damon. Ms. Damon is one of the individuals for whom Medicare approved coverage and reimbursement for an AAC device -- ***in 1986.*** After constant use for 10 years, that device ceased to function. Because her device no longer is manufactured or serviced, Ms. Damon purchased a LightWriter, a Category 2 AAC device, as its replacement. In 1999, Mr. Gibson exchanged e-mail messages with Ms. Damon to explain why she now had to pursue numerous appeals even though Medicare had already covered and reimbursed her for the previous AAC device. Ms. Damon lacks the use of her hands, and instead makes physical contact direct selection with her LightWriter by means of a head-pointer. Ms. Damon's use of this method led to her use "Ms.Unicorn" as her E-mail name. (Ms. Damon had an ALJ hearing for her replacement device on June 1, 2000. A decision is pending.)

When considering an individual's physical ability to use an AAC device, an individualized, structured assessment is performed. By contrast, no standardized battery is performed. Instead, the SLP, and as necessary, other professionals such as an occupational therapist and/or rehabilitation engineer, use demonstration and experimentation to identify the most effective and efficient means of access to the AAC device. The *Formal Request* discusses the possibility of joint-decision making in Section 3: it notes, repeatedly, that "[t]his portion of the AAC assessment is often conducted in collaboration with other allied-health professionals . . . ." ASHA acknowledged this shared assessment and decision making role almost 20 years ago: in its first position statement on AAC intervention, ASHA stated that inter-disciplinary evaluation teams may be appropriate, but that the SLP is to play "[t]he central role in initiating and coordinating the services of this team. . . ." (ASHA, 1981). An AAC intervention "consensus conference" stated: "AAC intervention is most effective when a team approach is used." (NIDRR, 1992). Both the role of a multi-disciplinary team, and the SLP as the leader of that team also are common concepts in existing AAC device coverage policies submitted with the *Formal Request*. (USSAAC "Model AAC Coverage Policy", 1995(Appendix II-A); Medi-Cal AAC Device

Coverage Policy, (1996)(Appendix III, Tab 1, p. 1); Maine Medicaid AAC Coverage Policy (1991)(Appendix III, Tab 1, §B(3)); Michigan Medicaid AAC Coverage Policy (1994)(Appendix III, Tab 1, at 11-8.1); New York Medicaid AAC Coverage Policy (1991)(Appendix III, Tab 1, at p. 4); Ohio Medicaid AAC Coverage Policy (1993)(Appendix III, Tab 1, at § 5101:3-10-24(H)(2)).

The goal of the SLP's or joint SLP-OT/Rehab. Engineer effort is to identify the access method to the AAC device that allows the individual to create messages as quickly as possible, with the least amount of effort. The conclusions that are reached are based on individual clinical facts observed, and the professional judgment of the SLP and OT/Rehab engineer (if involved).

Outcome Studies

We will be providing additional information on this topic in the coming weeks.

2. NICD Sponsored AAC Research

HCFA's web-site stated:

> Of particular note in the supporting documentation, was a 1995 report detailing the recommendations of a workshop sponsored by the National Institute on Deafness and Other Communication Disorders, dealing with AAC research priorities. The recommendations included:
>
> • Study of the influence of user variability on AAC use;
>
> • Development of tools and strategies to validly and reliably measure communicative, operational, linguistic, strategic, and social competence of children and adults who use AACs (sic);
>
> • Investigation of the effectiveness of AACs (sic) by user age, etiology (of impairment) and social context "to determine those factors that are related to success and failure of AAC use.
>
> The results of the suggested research were not included in the supporting material submitted. We recognize that these devices do not lend themselves to randomized clinical trials, which are the gold standard of scientific evidence, but we need more material reporting results for multiple patients over extended periods in order to develop specific coverage guidelines for AACs .

Response:

This paragraph refers to Beukelman and Ansel (1995), which had been submitted with the *Formal Request* at Appendix II-A. This article describes a meeting of AAC professionals and officials at NICD at which it was agreed to expand the extra-mural research grant agenda for NICD to include topics related to AAC interventions. The web-site states that the results of this research were not presented in the *Formal Request*. According to Beth Ansel, formerly the director of extra-mural research programs at NICD, and now the deputy to Dr. Michael Weinrich, only a few AAC related research grants have been approved, and those efforts have not yet been completed.

In response to the statement in this paragraph that HCFA needs more material reporting results from multiple patients over extended periods in order to develop specific coverage guidelines for AAC devices, we will be providing additional information in the coming weeks.

3. Physician Input

The HCFA web-site states:

> We are particularly desirous of receiving input from the physician community treating patients whose disabling conditions include severe speech impairment. We seek input from the entire health care team likely to be providing services to a patient with severe speech impairment, including the attending physician, specialists such as neurologists, primary care givers, and other therapists. The patient's attempts to make his or her needs for medical care known to these involved parties is the essence of the medical necessity for an AAC device.

Response:

Physician Input:

We are attaching at Tab 5 letters from the American Medical Association, American Academy of Neurology and the American Academy of Physical Medicine and Rehabilitation. Also included at Tab 5 are letters from physicians who direct clinics serving individuals with Amyotrophic Lateral Sclerosis and other physicians who serve as medical advisors to the Brain Injury Association, one of the organizations participating in the Formal Request.

We also reiterate our offer to convene for HCFA staff a panel of nationally prominent physicians who treat patients whose conditions include severe communication disability.

Medical Need for AAC Devices

The intent of the last sentence of this paragraph, regarding the patient's attempting to make his/her needs known to medical care providers as being the "essence of medical necessity" for an AAC device, is not clear. If this sentence is meant to be construed such that the medical necessity for AAC devices is limited to communication with medical care givers about medical care information, this premise is incorrect.

We have discussed this topic with HCFA staff on several occasions, including: the initial conference call about AAC device coverage policy reform on June 17, 1999, and the in-service presentation on February 24, 2000. This issue is discussed in the *Formal Request*, (in Section 4, at footnote 17 on pages 53-54); and in the materials that accompanied the *Formal Request* (*see* the state Medicaid AAC device coverage policies in Appendix III, Tab 1). It also is expressly contradicted by the letter submitted by the American Academy of Neurology, attached at Tab 5. That letter states:

> it would be completely inappropriate for HCFA to link coverage for such devices to only communication between physicians and patients.

The medical need to communicate is ***not*** dependent on the need to communicate medical care information. During the conference call with HCFA staff and Henry Claypool on June 17, 1999, David Beukelman, Ph.D. and Sarah Blackstone, Ph.D. explained the error in this conclusion. This explanation was re-stated at the February 24, 2000 in-service presentation in response to a

question by Mr. Wardwell. It also was explained in correspondence to HCFA submitted by the American Academy of Neurology, excerpted above (March 22, 2000) and the American Speech-Language-Hearing Association (March 20, 2000).

As was explained to HCFA staff, no Medicare requirement requires that Medicare reimbursed treatment for severe communication disabilities be directed exclusively or specifically to communication of medical information to medical care providers.. No such coverage criteria exist for speech-language pathology services, Medicare Intermediary Manual, § 3905.3; Medicare Hospital Manual, § 446, or for speech related prosthetic devices, such as the artificial larynx, tracheostomy speaking valve, or Ultra Voice. For example, there is no requirement that an individual be shown unable to communicate effectively with his or her physician through writing before SLP services or any of these speech-related prostheses are provided. Likewise, there is no requirement for specific proof of a communication barrier between patient and physician before Medicare will provide funding for a cochlear implant, a device which aids receptive, as compared to expressive communication.

During a conference call on May 10, Laurie Feinberg, M.D., of CHPP asserted that this requirement is rooted in the Medicare "reasonable and necessary" standard. To the contrary, the "reasonable and necessary" provision provides the most obvious illustration of why a "medical speak equals medical need" conclusion is ***not*** correct. A single individual can be shown to require all three types of expressive communication treatment services that are covered by Medicare: SLP services; an artificial larynx; and an AAC device. A person with a throat cancer may experience speaking difficulties which lead to provision of Medicare funded speech-language pathology services. The functional goals which must be set for those services, as described in the Medicare SLP coverage guidance include restoring the patient to full conversational communication, a standard vastly broader than "medical speak." If the cancer spreads to the larynx and a laryngectomy is performed, the patient can be provided an artificial larynx, which is expressly covered by a Medicare national coverage decision. Nothing in that NCD states that an artificial larynx will be reasonable and necessary only when it will facilitate "medical speak."

Finally, if the cancer spreads to the patient's tongue, and a glossectomy is necessary, the artificial larynx will have to be replaced by an AAC device, such as a category 2 or category 3 device as described in the *Formal Request*. These devices will permit achievement of the same functional goal as both other types of speech-related treatment: restoration of full conversational communication. No basis exists, however, for the standard of "reasonable and necessary" now to change for this individual to exclude treatment that will permit ongoing achievement of "full conversational communication" and instead now be limited to "medical speak."

The "essence" of medical need for an AAC device is to enable an individual to meet the communication needs arising in the course of daily activities. This is the functional goal stated repeatedly throughout the *Formal Request*, the letters attached at Tab 5, the "consensus conference" related to AAC intervention (NIDRR, 1992), and the state Medicaid policies attached at Appendix III, Tab I of the Formal Request. It is the only standard that is consistent with professional policy, practice, published literature, and coverage policies and practices of other funding sources. It also is the consistently held standard by Medicare administrative law judges when they have reviewed Medicare AAC device appeals. These decisions were attached to the *Formal Request* at Appendix III.

4. Severe Impairments; AAC Device Demand Estimate

The HCFA web-site states:

> We are very interested in a usable definition of "severe." We have seen estimates that up to 4.5 million people in the United States suffer from speech impairment, but we do not know how severe these impairments are or which of them might benefit from an AAC. We seek scientific proof or clinical rationale that might support the use of AACs for an appropriate and clearly defined patient population. The population might be defined by disease entity with severity indices. We do not wish to cover these devices in populations where they have no medical benefit or where there is no evidence of improvement for a defined population. We need information showing that these devices have a positive health outcome.

Response

Severe Impairments

This comment is addressed in response # 1.

AAC Demand Estimates

We understand that HCFA staff obtained the 4.5 million population estimate from a disability organization website. However, upon investigation, we are unable to establish any basis for that figure. In contrast, we believe the appropriate estimate of total need for AAC devices among the Medicare population (prevalence) to be 46,000-47,000, with an annualized demand of a few hundred devices (annualized prevalence).

The *Formal Request* discusses estimated demand for AAC devices, based on a search and review of published literature. *Formal Request*, at Appendix I, Tab 5. Two conclusions resulted from this investigation: first, that there is no precise estimate of the number of individuals who require AAC devices; and second, that published studies have examined variables which are not synonyms for AAC device need, but which define broader populations. Thus, merely applying existing published study results will over-estimate actual AAC device demand. Moreover, even as to these broader populations, the published literature yields prevalence estimates that vary widely. (Beukelman and Mirenda, 1998).

In addition, for some estimates no clear evidentiary basis exists. This includes the 4.5 million person estimate posted at the HCFA web-site. We are aware of no study or other objective source of the accuracy of this figure. Other estimates by United Cerebral Palsy Associations (UCPA) state a figure of 750,000-1,500,000, which is 3 to 6 times smaller than the figure posted at the HCFA web-site. The HCFA web-site estimate is more than double the long-standing estimate by ASHA that there are 2 million Americans with severe communication impairments (ASHA, 1991), and almost double the 1996 estimate by the United States Bureau of the Census that there are 2.5 million Americans older than age 15 who experience difficulty having their speech understood by others. (Census Bureau, 1996). It also is almost double the prevalence published by Beukelman and Ansel (1995). The difference between the HCFA web-site estimate and the estimate in this study is not addressed even though this study is expressly referenced elsewhere in the web-site posting.

The Census Bureau estimate also raises another point that was of concern to the authors of the *Formal Request* but is not addressed in the HCFA web-site: population comparability. The

authors of the *Formal Request* attempted to gather estimates of demand for AAC devices by individuals who are comparable to Medicare beneficiaries, i.e., adults. There is no indication that the UCPA estimate is of adults or of individuals otherwise comparable to Medicare beneficiaries.

Upon review of the published data, the authors of the *Formal Request* determined -- and explained at Appendix I, Tab 5 -- that the best evidence on which to prepare demand estimates is a published study by Bloomberg and Johnson (1990). Applying the data from that study, the *Formal Request* estimates that total demand for AAC devices is between 46,000 - 47,000 individuals (prevalence), and provides a further estimate of annualized demand of only a few hundred per year (annualized prevalence).

5. Role of Physical Condition Diagnosis

The HCFA web-site states:

> What are the specific chronic disease entities, including variants within such entities, which result in complete, permanent loss of meaningful oral communication, but which do not impair cognitive and physical ability to use AAC equipment successfully? Such impairments and variants should have defined diagnostic criteria which make a definite diagnosis possible and such criteria should be included in the response.

Response:

On advice from Dr. Michael Weinrich, we have included as the first clinical indicator in the revised AAC device coverage criteria, attached as Tab 1, a non-exclusive list of physical condition diagnoses that are associated with severe communication disability. As explained in Response # 1, above, the treating physician is required to certify the existence of such a physical condition diagnosis prior to making the referral for SLP evaluation.

Also discussed at Response # 1 is the manner in which the severity of communication disability, cognitive abilities and physical abilities are assessed.

6. Identification of Symptomatic or Functional Deficits

The HCFA web-site states:

> What are the specific symptomatic or functional deficits for which AAC devices are useful? The original request was for a population that had loss of speech, characterized as dysarthria, apraxia or aphasia. We are concerned that this list is both too inclusive and also exclusive of populations that could benefit, and thus further specification and refinement are needed. For example, patients who are aphonic on a long term basis due to laryngeal disorders may be eligible for an AAC device, but are not discussed in the supporting material received. On the other hand, we are not convinced that all patients with aphasia could benefit from an AAC. Language impairment could occur as a component manifestation of several neurological disorders, which produce cognitive deficits. This merits particular consideration because cognitive impairment will impede learning and the ability to operate any device, including an AAC device.

Response

As described in Response # 1, and Tab 1, objective test measures have been added as proposed clinical indicators to more specifically delineate the symptomatic or functional deficits which warrant further SLP evaluation and consideration of the need for an AAC device .

Response # 1 also addresses the communication diagnoses which support investigation and consideration of AAC device need. Consistent with the suggestion in the HCFA web-site, we have added aphonia as a communication diagnosis in the proposed coverage criteria.

Response # 1 also clarifies the characteristics of individuals with aphasia for whom consideration of AAC device need is appropriate. The characteristics of this population are consistent with the professional literature, actual clinical practice, and the research-based conclusions and opinions of Dr. Weinrich and Dr. Beukelman.

7. Cognitive Testing & Outcomes

The HCFA web-site states:

> We are interested in knowing if speech language pathologists or physicians with whom they work have developed metrics that correlate cognitive scales with outcomes after AAC use. If so, did the outcomes positively trend at certain levels of cognition? Are there any controlled studies comparing the outcomes and benefits of AACs with other interventions which may foster language such as additional care giver attention and provision of social support? There was some material submitted by the requestor indicating that improved social support did foster communication, but no comparison to AAC use was presented.

Response

Consideration of cognitive abilities in the comprehensive SLP/AAC assessment process is described in Response # 1.

In addition, no validated tests exist that correlate cognitive scales with outcomes after AAC device use. The process of determining AAC need and recommending an AAC device and the dynamic processes of communication are all too complex to suggest that a single point of measurement can predict successful outcomes.

There are no controlled studies of the type described in this paragraph.

8. Dysarthria Stages

The HCFA web-site states:

> Similarly, while the information provided did describe five stages of dysarthria and recommended coverage of the device beginning at stage III, no objective and quantifiable means of distinguishing between the five stages were presented. We would be interested in knowing if objective testing exists, which would permit such distinctions, and receiving descriptions of it, if available.

Response:

Response # 1 explains the tests and measures that have been included in the proposed AAC device coverage criteria to provide a more specific description of the individuals with severe dysarthria for whom further assessment and consideration of AAC device need is appropriate.

9. Exclusions

The HCFA web-site states:

> Information that might support development of exclusion criteria might address:
>
> Whether patients with some or all types of aphasia should be excluded from coverage of an AAC device. What types of chronic brain diseases should be excluded? How severe does the chronic brain disease have to be before a patient is incapable of use of these devices? How would we measure or define the severity of chronic brain failure or cognitive function? Should this be determined by neuro-psychiatric testing? If so, what test(s) would be accurate, reliable and valid?

Response:

Total Exclusion for Aphasia

There is no evidence on which to base a complete exclusion of aphasia from Medicare coverage of AAC devices. Response # 1 clarifies the characteristics of the population of individuals with aphasia for whom further investigation and assessment of AAC device need is appropriate. The clarification, as stated in Response # 1, was based on the discussion with Dr. Weinrich and is supported by his personal research activities as well as the published professional literature and an informal survey recently conducted by David Beukelman, Ph.D. The American Academy of Neurology and the other professional medical societies that reviewed the Formal Request all supported AAC device coverage for individuals with aphasia. The specific changes made to the coverage criterion were based on input from Audrey Holland, Ph.D., University of Arizona; Melanie Fried-Oken, Ph.D., Oregon Health Sciences University; Kathryn Garrett, Ph.D., Duquesne University; and Pam Mathy, Ph.D., and Kelly Ingram, Ph.D., both of Arizona State University, all of whom are involved in teaching and research about, and clinical treatment of individuals with aphasia.

Chronic Brain Failure

We are aware of no information that exists regarding appropriate exclusion criteria for chronic brain disease or failure.

10. Physician Testing

The HCFA web-site states:

> We believe that most of the disease entities for which coverage of AAC devices might be appropriate will require an neurologist's assessment of the etiology of the speech loss, the type of speech loss, and the presence of absence of excluding conditions before a specific recommendation for the equipment could be made. Comments on specific tests, if any, which should be included in that assessment to ensure that the patient has sufficient cognitive and physical capacity to effectively use AAC equipment are requested.

Response:

Physician Responsibilities in the Assessment Process

The description of the physician's role stated in the above quoted paragraph substitutes a neurologist for the speech-language pathologist in the AAC assessment process. No basis exists for this suggestion. Determination of the type, nature and extent of the communication impairment is uniformly recognized as the province of the speech-language pathologist, following the referral by the treating physician. Determination of the cognitive and physical capacity to use and benefit from an AAC device also is part of the SLP clinical assessment and decision making process. The physician checklist, which is addressed in Response # 1, and is attached at Tab 2, was developed by the American Academy of Neurology to address the physician role in the period before referral to an SLP is made. As noted in Response # 1, the physician role at the outset of the assessment process is now clearly defined: the treating physician is responsible for the physical condition diagnosis and completion of the checklist which supports SLP referral.

Also, as stated in Response # 1, both Dr. Weinrich and the American Academy of Neurology indicated that a patient's treating physician complete the required physical diagnostic report and checklist for SLP referral. In contrast to the implication in this paragraph, a neurologist is not the required medical professional to be involved.

Use of Objective Testing in the SLP Referral Process

The inquiry about reliance on "specific tests," is addressed by the April 25 letter from the American Academy of Neurology which states that physicians use no specific tests before referral is made for SLP or AAC evaluation. The physician checklist developed by the Academy of Neurology, at the suggestion of Dr. Weinrich, and attached at Tab 2 affirms this conclusion.

Significance of the Physical Condition Diagnosis

There are numerous references in the HCFA web-site comments, and there have been additional comments by Madeline Ulrich on April 7 and by other HCFA staff during the May 10 conference call that the medical or physical impairment diagnosis, as distinguished from the communication impairment diagnosis, is of primary importance in relation to AAC assessment, recommendation, provision and benefit. There is no support in the *Formal Request*, in actual clinical practice related to AAC intervention, or in any of the medical society or individual physician correspondence submitted to HCFA to support these comments.

This view also was not supported by Dr. Weinrich. He recognized that the seven physical condition diagnoses discussed in the *Formal Request* were merely illustrations of the conditions most closely associated with individuals who had AAC needs and who use AAC devices. He acknowledged that other neurologic conditions also cause dysarthria, apraxia and aphasia, and that the nature and severity of those communication impairments may give rise to AAC device need.

As is explained in Response # 1, Dr. Weinrich recommended that we include a list of most common physical condition diagnoses that are known to be associated with communication disability. He also stated this list should be non-exclusive. He did not believe that any individual should be *per se* excluded from further consideration and assessment of possible AAC device need on the basis of physical condition diagnosis.

The *Formal Request* addressed this topic in Section 3. AAC devices do not treat ALS or the other physical condition diagnoses that are identified in Section 3. The March 22 letter from the American Academy of Neurology stated this point directly. The Academy of Neurology letter stated:

> Augmentative and alternative communication devices are typically used for a variety of disease states that cannot be "treated" and where maximum improvement has already been reached. One respondent summarized that, "the use of the devices are not for treatment of the primary condition, but rather the effects of the condition."

The effects of the "condition"or physical condition diagnosis are the communication impairments: dysarthria, apraxia, aphasia and aphonia. AAC devices have long been recognized as treatment for the first three of these communication disabilities, which is discussed in Section 3 of the *Formal Request*. The American Medical Association letter dated March 21 stated that "Section 3 . . . is an excellent summary of the strong clinical evidence for the efficacy and effectiveness of AAC devices for the treatment of dysarthria, apraxia and aphasia."

11. Training

The HCFA web-site states:

> We would like recommendations as to the number of visits with a speech language pathologist which are necessary for training of the patient in the use of a particular AAC device and in customizing its features to meet the patient's medical needs.

Response:

We will be providing a response to this information request in the next few weeks.

12. Objective Measures Related to AAC Benefit

The HCFA web-site states:

> Can the speech language community develop valid and reliable objective measures for assessing the benefits realized from an AAC device in each patient at specified periods after the device has been provided. We are interested in comments from speech language pathologists, treating physicians and ancillary personnel on this issue. This may be an ongoing process. We do not address duration of use, but this may be dealt with by other components within HCFA as a condition of payment.

Response:

The benefits provided by AAC devices can be stated clearly: they enable individuals with severe communication disability to meet their daily communication needs, when those individuals would otherwise be unable to do so using natural communication methods. That is the treatment role and treatment benefit provided by AAC devices.

That an individual is able to meet those communication needs provides secondary benefits across the broad range of individual daily activities. They increase the effectiveness of communication with familiar as well as unfamiliar communication partners, including asking and answering questions, and providing information. AAC devices will facilitate increased independence of the

AAC device user, by enabling specific needs to be met (whether related to medical care, daily care routines; ordering in a restaurant or securing goods and services in the community; talking on the telephone). For those individuals who use AAC devices in school or work settings, permits increased productivity. And, AAC device use increases the ability of their users to be included in community-based activities, whether social, recreational, religious, political or for other purposes.

The benefits that AAC devices provide to their users will be reported in greater detail, from outcomes-related information, in the next few weeks.

PROPOSED COVERAGE CRITERIA FOR AAC DEVICES
PROPOSED WORDING FOR AAC DEVICE NATIONAL COVERAGE DECISION

Augmentative & Alternative Communication Devices

HCPCS Codes:
Equipment:

E xxx 1: AAC devices with digitized speech output
E xxx 2: AAC devices with synthesized speech output, which require message formulation by spelling and device access by physical contact direct selection techniques
E xxx 3 AAC devices with synthesized speech output, which permit multiple methods of message formulation and multiple methods of device access

Accessories:

E xxx 4-1: AAC Accessories: access technologies, direct and indirect
E xxx 4-2: AAC Accessories: mounting systems
E xxx 4-3: AAC Accessories: carrying cases
E xxx 4-4: AAC Accessories: power supplies
E xxx 4-5: AAC Software

HCPCS Modifiers for AAC devices with digitized speech output

ZV: AAC devices with digitized speech output with less than 4 minutes recording time
ZW: AAC devices with digitized speech output with 4- 8 minutes recording time
ZX: AAC devices with digitized speech output with 9-16 minutes recording time
ZY: AAC devices with digitized speech output with 17-32 minutes recording time
ZZ: AAC devices with digitized speech output with more than 32 minutes recording time

Benefit Category: Durable Medical Equipment

Definitions:

Augmentative & Alternative Communication (AAC) devices are electronic devices that provide treatment for severe dysarthria, severe apraxia of speech, mild to moderate aphasia with severe apraxia, or aphonia, when, due to those communication impairments, an individual is not able to meet the communication needs that arise in the course of current and projected future daily activities. AAC devices are covered as durable medical equipment when incorporated into a speech- language pathology treatment plan, and when it is determined by a speech-language pathology assessment that an individual is unable to meet the communication needs arising in the course of daily activities using natural communication techniques.

AAC devices include electronic devices that are: a) dedicated communication devices; and b) portable computers that have been modified to serve as an individual's communication device. The term AAC accessories means device-related components, software, and accessories that are necessary additions to an AAC device, based on the nature and severity of the beneficiary's disability, to permit its effective and efficient use.

An AAC device will be covered by Medicare as an item of durable medical equipment when all of the following are met: a) the AAC device is recommended by a speech-language pathologist who asserts in writing that he or she has no financial interest in the sale of the AAC device; b) the

speech-language pathologist's recommendation is contained in a narrative report based on a complete assessment; b) it is incorporated into a speech-language pathology treatment plan stating the functional communication goals to be achieved with the AAC device; c) it is prescribed by the beneficiary's physician; and d) it is supported by a completed certificate of medical necessity.

Coverage and Payment Rules

Code E xxx 1 is covered if the individual meets:

a. criteria 1-6 but not
b. criteria 7, 8 and 9

Code E xxx 2 is covered if the individual meets:

a. criteria 1-8 and 10 but not
b. criteria 9, 11, and 12

Code E xxx 3 is covered if the individual meets:

a. criteria 1-7 and
b. criteria 9

Clinical Criteria:

1. The individual has been evaluated by a physician and diagnosed with one of the following conditions, or another condition with which severe communication impairment is associated:

Degenerative Diseases:

Amyotrophic lateral sclerosis
Other Motor Neuron Diseases (inclusive)
Multiple sclerosis
Huntington's disease
Parkinson's disease
Parkinson's Plus syndromes (inclusive)
Cerebellar degenerative diseases (Inclusive)
  Friedreich's
  Spinocerebellar
Wilson's disease & Other Genetic-metabolic conditions (Inclusive)
Nervous System tumors (Selected)
Myasthenia Gravis

Stable Conditions (STABLE--RECOVERING)

Brainstem stroke
Locked-in-syndrome
Cerebral Palsy
Dystonia's (Inclusive)
Guillian-Barre' syndrome
Traumatic brain injury
Cerebral Vascular Accident

2. The physician makes a referral for speech-language pathology and/or augmentative communication evaluation based on the existence of the signs and symptoms of communication impairment stated on the accompanying physicians checklist (Attachment A).

3. The individual has been evaluated by a Speech-Language Pathologist and diagnosed with one of the following communication impairments: dysarthria, apraxia; aphasia or aphonia.

4. The severity of the individual's dysarthria, apraxia, aphasia or aphonia is such that the individual's communication needs that arise in the course of current and projected daily activities cannot be met using natural communication methods.

a) For individuals with dysarthria, the SLP must conclude the severity of this condition is at Stages 4 or 5:

i) based on a finding that the individual received a score less than or equal to 90 % on the Sentence Intelligibility Test or the Sentence Test of Intelligibility of Dysarthric Speech; or

ii) based on a finding that the individual has been found to be functioning at Level 1, Level 2, or Level 3 on the Motor Speech Functional Communication Measure (FCM) Section of the National Outcomes Measurement System; or

iii) for individuals with Amyotrophic Lateral Sclerosis (ALS), based on a finding that the individual's rate of intelligible word production is less than or equal to 130 words per minute.

b) For individuals with a diagnosis of Apraxia, the SLP must conclude that the individual has a severe to profound apraxia.

To quantify apraxia severity, the SLP may use the expressive sub-tests and cutoff scores from the of the WAB or the BDAE (described below) or a standardized apraxia battery for adults (e.g., the Apraxia Battery for Adults (ABA-2, B.L. Dabul, Pro-ed publishers) which yields a severity rating based on normative data. The individual's severity rating must fall within the severe to profound range.

c) For individuals with a diagnosis of Aphasia, the SLP must conclude that the individual has an insignificant to a moderate impairment in language comprehension coupled with a severe impairment in expressive communication as measured by either the Western Aphasia Battery (WAB) (1982), or the Boston Diagnostic Aphasia Examination (BDAE) (1983). The impairment in expressive communication may be due to a severe apraxia, a severe expressive language deficit, or a combination of these impairments.

i) *Language Comprehension Impairment*

Western Aphasia Battery: Administer Section II--*Auditory Verbal Comprehension*. The individual must receive an overall score of 4 or higher.

Boston Diagnostic Aphasia Examination: Administer Section II, *Auditory Comprehension*. The individual must receive an overall percentile ranking in the 30th percentile or greater.

ii) *Expressive Communication Impairment*

Western Aphasia Battery: Administer Section I, *Spontaneous Speech*, Scale B, *Fluency, Grammatical Competence and*

Paraphasias. Individuals with a severity score of five or below, are classified as having a severe expressive communication impairment.

Boston Diagnostic Aphasia Examination: Administer Section I, *Conversational and Expository Speech* and Section III, *Oral Expression*, Sub-test A#2), *Verbal Agility*. Using the *Rating Profile of Speech Characteristics*, determine an overall severity rating (one: severe impairment to seven: insignificant impairment). An overall rating of four or lower indicates severe expressive communication impairment.

d) For individuals with a diagnosis of aphonia, the SLP must conclude that the individual is not able to use natural communication, amplification devices or an artificial larynx (electronic speech aid) to meet daily communication needs.

5. The individual requires a speech output communication device to meet his/her functional communication goals.

6. The individual possesses the cognitive, functional communication ability to use a speech output communication device to meet daily communication needs.

a) For individuals diagnosed with traumatic brain injury, the individual has been determined to have cognitive functioning at Rancho Scale, Level VI-VIII (AAC intervention, late stages).

7. The individual possesses the linguistic capability to formulate language (messages) independently.

8. The individual will produce messages most effectively and efficiently using spelling.

9. The individual will require an AAC device with extensive language storage capacity and rate enhancement features.

10. The individual will access the AAC device most effectively and efficiently by means of a physical contact direct selection technique, such as with a finger, other body part, stylus, hand held pointer, head stick or mouth stick.

11. The individual will access the AAC device most effectively and efficiently by means of an electronic accessory that permits direct selection.

12. The individual will access the AAC device most effectively and efficiently by means of an indirect selection technique (*e.g.*, scanning, Morse Code).

The speech-language pathologist's narrative report also must establish whether an individual for whom HCPCS Code E xxx 1-3 will require any AAC accessories.

For accessory code E xxx 4-5 to be covered, the individual must meet criteria 5 and 7 as listed above, and the certificate of medical necessity must specifically establish that the individual has access to specially adapted computer components and adaptations that will permit the individual's needs to be met solely by the use of AAC software.

Appropriate use of the Z_ modifier is the responsibility of the supplier billing the DMERC. This modifier identifies the device that fits within the HCPCS code E xxx 1.

A trial period of 30 days is required for all AAC devices within the HCPCS Code E xxx 3.