FORMAL REQUEST FOR NATIONAL COVERAGE DECISION FOR AUGMENTATIVE AND ALTERNATIVE COMMUNICATION DEVICES

Respectfully Submitted by:

American Speech-Language-Hearing Association

Amyotrophic Lateral Sclerosis Society

Brain Injury Association

Center on Disability & Health

Communication Aid Manufacturers Association

Communication Independence for the Neurologically Impaired

International Society for Augmentative & Alternative Communication

National Association of Protection & Advocacy Systems

National Multiple Sclerosis Society

RESNA

Sunrise Medical

United Cerebral Palsy Associations

United States Society for Augmentative & Alternative Communication

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Nature of Request:

This Formal Request seeks Medicare coverage of Augmentative and Alternative Communication (AAC) devices. These devices treat certain individuals with severe communication impairments, such as dysarthria, apraxia, and aphasia, attendant to motor disorders and such neurologic conditions as amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease), cerebral palsy, Parkinson disease, locked-in syndrome, multiple sclerosis, and traumatic brain injury.

Current Medicare and Medicaid Coverage Status of AAC Devices:

The Medicare Coverage Issues Appendix, at an unknown point in time, labeled AAC devices as 'communicators' -- not an appropriate term -- and classified them as noncovered convenience items. The Health Care Financing Administration (HCFA), through the Freedom of Information Act, has acknowledged that it has no documentation of the types of devices considered or the basis for the noncoverage decision. In contrast, every Medicaid program covers AAC devices, either as durable medical equipment or prosthetic devices, or as necessary equipment within the speech-language pathology benefit category.

FDA Status:

Since 1983, the Food and Drug Administration (FDA) has classified AAC devices as 'powered communication systems.' 21 C.F.R. § 890.3710.

Estimated Total Prevalence of AAC Device Need Among Medicare Beneficiaries:

47,000 individuals.

Requested Benefit Category and Payment Classification:

AAC devices appropriately are classified as items of durable medical equipment (DME), which are routinely purchased. They meet the specific regulatory criteria necessary for DME coverage (they can withstand repeated use, serve a medical purpose of treating severe communication disabilities, are not useful in the absence of illness or injury, and are appropriate for home use), as well as the Medicare reasonable and necessary statutory standard, by permitting individuals with severe dysarthria, apraxia, or aphasia to communicate.

Requested Codes:

The HCPCS Alpha-Numeric Editorial Panel issued Code E1900, effective January 1, 2000, for a 'speech communication device,' with the following descriptor: 'synthesized speech augmentative communication device with dynamic display.' However, the universe of AAC devices is best covered by three codes, as follows:

Code 1: AAC Devices with Digitized Speech Output

Code 2: AAC Devices with Synthesized Speech Output which (a) Require Message Formulation by Spelling, and (b) Require Access by Physical Contact Direct Selection Techniques

Code 3: AAC Devices with Synthesized Speech Output which Permit Multiple Methods of Message Formulation and Multiple Methods of Access. (This code will include all AAC devices covered by HCPCS Code E1900.)

Codes for Accessories: access technologies; mounting systems; supplemental power sources; carrying cases; and software.

Modifiers for Code 1

Requested Coverage Criteria:

HCFA should require an assessment by a qualified speech language pathologist before Medicare coverage of an AAC device would be deemed appropriate, with the determination of the appropriate device based on nine clinical criteria:

1. Communication disability with a diagnosis of severe dysarthria, apraxia, and/or aphasia

2. Communication needs that cannot be met using natural communication methods

3. Need for speech output communication device to meet specified functional communication goals

4. Linguistic capability for independent language (messages) formulation

5. Most efficient and effective technique for message production is spelling

6. Need for a device with extensive language storage capacity and rate enhancement features

7. Most efficient and effective access technique is via physical contact direct selection

8. Most efficient and effective access technique is via an electronic accessory permitting direct selection

9. Most efficient and effective access technique is via indirect selection (*e.g.*, scanning, Morse Code)

SECTION 2: EXECUTIVE SUMMARY

I. INTRODUCTION

This is a Formal Request for an Augmentative and Alternative Communication (AAC) Devices National Coverage Decision (NCD). These materials demonstrate that the past Medicare noncoverage decision related to AAC devices should be withdrawn and replaced with this proposed AAC Device NCD, which is based on professionally and programmatically sound criteria. As discussed below, the Health Care Financing Administration (HCFA) has no records of the basis or rationale for the noncoverage decision, and the noncoverage decision is inconsistent with 1) Medicare coverage policy and practices for items and services that treat the same conditions and address identical treatment goals (e.g., SLP services; laryngoplasty; artificial larynx; tracheostomy speaking valves); 2) a substantial volume of peer reviewed professional literature, policy and clinical practice; and 3) policies and practices of all state Medicaid programs and an overwhelming number of other public as well as private third party reimbursement programs. This Formal Request consists of six sections and three Appendices.

II. USE OF AAC DEVICES

AAC devices fall within a class of durable medical equipment that generally is recognized as appropriate treatment for, and has become the standard practice in, the treatment of individuals with severe communication impairments, such as dysarthria, apraxia, and aphasia. The Food and Drug Administration (FDA) classifies AAC devices as 'powered communication systems.' AAC devices are reasonable and necessary treatment for individuals with dysarthria, apraxia, and/or aphasia, when these conditions are of such severity that, without an AAC device, the individual will lack 'functional' or 'meaningful' communication, *i.e.* when these speech (dysarthria, apraxia) and language (aphasia) disabilities interfere with the individual's ability to meet the communication needs arising in the course of current and projected daily activities through natural communication techniques, such as speech, writing, and/or gestures. These severe communication disabilities arise among small numbers of individuals with primary physical impairments of amyotrophic lateral sclerosis, also known as ALS or Lou Gehrig's Disease; cerebral palsy; locked-in-syndrome; multiple sclerosis; Parkinson disease; brain-stem stroke; cortical stroke; progressive aphasia; and traumatic brain injury. Based on demographic studies of individuals with 'severe communication impairment,' approximately 47,000 Medicare beneficiaries require AAC devices because natural communication methods insufficiently meet their daily communication needs.

When, due to disability, effective natural communication is not possible, AAC devices provide individuals with severe communication impairments the 'access to life' that professional literature identifies as being lost or denied. (Beukelman & Garrett, 1988). AAC devices provide opportunities to lead extraordinary lives: for example, world-renowned physicist Dr. Stephen Hawking and Bob Williams, the Deputy Assistant Secretary of Health & Human Services for Planning and Analysis, use AAC devices to communicate. Certain individuals using AAC devices such as Julia Tavalaro and Ruth Sienkiewicz-Mercer, discussed later in more detail, have made a remarkable transformations from being considered brain-dead or hopeless institutional cases to being recognized as intelligent, highly capable individuals and authors. Among other accomplishments, Ms. Sienkiewicz-Mercer married and successfully advocated for the closure of the institution where her needs and abilities had been neglected for many years. More typical cases include individuals such as Celia Cooper, who has ALS. Having lost the ability to speak due to ALS, Mrs. Cooper also lost the ability to communicate with her husband, children, grandchildren and friends, to run her household, to be left alone, or to negotiate community-based activities. Through the use of an AAC device, she regained the ability to perform these quite ordinary activities that adults without communication disabilities take for granted.

AAC devices are very effective in providing functional communication when speech is no longer intelligible. Users of AAC devices have a high degree of satisfaction with the communication opportunities they provide. AAC devices enable individuals to engage in the ordinary communication that arises in the course of their daily activities, which is consistent with the Medicare coverage requirements for all other forms of speech related services. Medicare's speech-language pathology services guidance recognizes that an individual's functional goals may range from speech that permits expressions of wants and needs to a caregiver to full conversational communication.

A. Summary Of Medical Evidence Related To AAC Treatment

AAC devices are recognized as appropriate treatment for, and have become standard practice in treatment of, individuals with severe dysarthria, apraxia, and aphasia. These speech (dysarthria, apraxia) and language (aphasia) conditions each produce a wide range of adverse effects on the ability to communicate. For the vast majority of individuals with these conditions, traditional speech-language pathology treatment techniques directed toward improving natural speech methods will be sufficient to enable them to meet daily communication needs. For a small number of individuals with these conditions however, estimated to be fewer than 47,000 Medicare beneficiaries, natural communication methods are insufficient to meet their daily communication needs, and for them, AAC treatment techniques, including AAC devices are necessary.

1. Medical Conditions Requiring AAC Devices: Dysarthria, Apraxia, And Aphasia

Dysarthria: The dysarthrias are a group of motor disorders that affect the ability of the vocal organs to execute the motor instructions required to produce intelligible speech. As a result, dysarthric speech is characterized by problems with articulation (production of speech sounds), voicing (volume and quality of speech), and prosody (speech rate, rhythm and naturalness), which interfere with speech intelligibility. Dysarthria is associated with many neurologic conditions including amyotrophic lateral sclerosis (also known as ALS or Lou Gehrig's disease), cerebral palsy, Parkinson disease, locked-in-syndrome, multiple sclerosis, and traumatic brain injury. For some individuals with severe dysarthria or anarthria (the complete lack of speech), the use of natural speech is not a realistic goal of intervention. (Yorkston, *et al.* 1999). For this small number of individuals, AAC devices are appropriate. An individual with severe dysarthria is able to formulate an intent to communicate, *i.e.*, formulate a thought, linguistically encode it appropriately as a message, and program the motor sequence necessary to produce the message as speech, but the body is unable, due to disability, to execute those commands that control speech production. An AAC device permits the individual's intent to speak to be fulfilled. It is generally accepted in professional practice that carefully selected

AAC devices are critical in offering an effective means for persons with severe dysarthria to meet the communication needs arising in their daily activities.

Apraxia: Acquired apraxia of speech is a term used to refer to a speech disorder, resulting from brain injury, that is characterized by changes in articulation and prosody. The disorder stems from a deficit in the planning and programming of the sequence of movements for speech and occurs despite the normal movement of the same muscles when speech is not involved. The most common cause of apraxia is stroke, although it also may occur with tumor or traumatic brain injury. Apraxia rarely occurs as an isolated disorder. When severe apraxia is present, it almost always co-exists with aphasia. It co-exists with dysarthria far less frequently. An individual with severe apraxia may produce no speech or perhaps a few stereotypical utterances that may or may not be meaningful. Imitation of even very simple utterances ('me,' 'no,' 'bye') is difficult. AAC devices are recognized in the professional literature and practice as appropriate treatment for severe apraxia, particularly those devices that are easily transported by ambulatory individuals, those that do not require spontaneous spelling skills to prepare messages, and those that allow individualized rates of speech, vocabulary, and symbol sets.

Aphasia: Aphasia is the impairment of an individual's ability to understand and formulate language as a result of brain damage, typically involving the language-dominant cerebral hemisphere. Depending on its severity, aphasia can significantly affect an individual's ability to converse, exchange information, and in some cases, to communicate basic needs. With aphasia, language and often communication are permanently altered. By far the most common cause of aphasia is stroke, although aphasia may also result from brain tumors, head injuries, or other insults to the areas of the brain that mediate language processing. AAC devices enable individuals with severe aphasia to express basic needs, to communicate functional needs more specifically, to participate more fully in social exchanges, to become more independent in the community, and to talk on the telephone. In a smaller number of cases, aphasic individuals with cognitive-linguistic abilities, partner support, and extensive vocabulary needs will require AAC devices with synthesized speech output and that permit multiple means of message generation.

2. Clinical Decision Making: Matching The Device To The Individual

Selecting the appropriate AAC device for an individual requires an understanding of the technology as well as expertise in the types of speech and language impairments that interfere with functional communication. A comprehensive assessment is conducted by a speech language pathologist (SLP), with as needed input from other allied health professionals. The assessment is the mechanism utilized to identify a need for an AAC device, and to confirm that the most appropriate AAC device is recommended, so that the individual will be able to meet his or her daily communication needs. The AAC assessment involves six steps:

1. determining current functional communication levels;
2. predicting future levels of communication effectiveness;
3. identifying functional communication goals and treatment approaches;
4. selecting AAC treatment approaches;

5. selecting an AAC device and accessories; and

6. procuring training and follow up.

The outcome of the assessment process is a narrative report that includes an AAC treatment plan identifying the functional communication goals the individual is expected to achieve with the AAC device. The treatment plan and functional communication goals are based on the clinical factors presented and the application of the SLP's professional judgment. After completing the assessment, and reviewing nine clinical indicators,[1] which address the need for treatment and device selection, the SLP may recommend, where indicated, an AAC device from one of the three categories of devices, and as needed, AAC accessories. The SLP then sends the narrative report to the individual's treating physician, who then prescribes AAC treatment and completes the certificate of medical necessity.

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1 The nine clinical indicators are as follows:

1. The individual has a communication disability with a diagnosis of severe dysarthria, apraxia, and/or aphasia.

2. The individual's communication needs that arise in the course of current and projected daily activities cannot be met using natural communication methods.

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

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

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

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

7. 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.

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

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

III. MEDICARE COVERAGE OF AAC DEVICES AS ITEMS OF DURABLE MEDICAL EQUIPMENT IS APPROPRIATE

AAC devices meet the Medicare statutory standard as 'reasonable and necessary' to treat individuals with severe communication impairments. The devices are already deemed reasonable and necessary by every state Medicaid program, as well as by the Veterans Administration, TriCare, and countless private insurers.

AAC devices further meet the Medicare regulatory requirements to be classified as items of durable medical equipment (DME). Indeed, they are already so classified by numerous Medicaid programs which employ DME definitions identical to Medicare's definition. First, AAC devices are durable. Second, AAC intervention serves a medical purpose. AAC devices are long recognized as a speech-language pathology treatment technique or methodology, and use of AAC devices serves the medical purpose of treating severe dysarthria, apraxia and/or asphasia when it is determined that other speech-language pathology treatment techniques directed to natural communication methods will not be sufficient to enable the individual to meet daily communication needs.

Third, AAC devices are not useful absent an illness or injury. Communicating with an AAC device provides profound benefits to an individual with severe communication disabilities, but it is much slower and less efficient than verbal communication. In short, no one uses an AAC device in the absence of severe communication disability. AAC devices are designed, marketed, and sold exclusively to individuals with severe communication disabilities. Fourth, and finally, AAC devices are intended for home use, permitting an individual with severe communication disability to meet daily communication needs at home and wherever else those needs arise.

By contrast, the current Medicare guidance related to AAC devices states that they are not durable medical equipment and should be denied as 'convenience items.' CIM § 60-9. This guidance is ripe for re-review, as HCFA staff acknowledged in June 1999 during early discussions on this Formal Request.

First, the basis for the noncoverage decision is not known. After multiple searches for records, HCFA staff has reported that none can be found. Moreover, the conclusions stated in this guidance are profoundly flawed:

- The 'convenience item' conclusion stands in stark contrast to a great volume of medical literature, of professional policy and practice, of the policy and practice of other health based benefits programs (all state Medicaid programs, hundreds of health insurance and health benefits plan providers, The Department of Veterans Affairs and CHAMPUS (now Tri-Care)), and of the uniform decisions of Medicare administrative law judges, who are permitted to examine this guidance as part of their decision making responsibilities.

- The 'convenience item' conclusion also is inconsistent with Medicare coverage and payment for speech-language pathology services and other treatment, such as larynogoplasty, as well as such speech-related devices as the artificial larynx, Ultra Voice and tracheostomy speaking valve. By covering those treatments and devices, Medicare clearly does not consider either the speech function, or devices that aid the speech function, as 'conveniences.' Indeed, the speech function generally is recognized as 'vital' and as the primary physical functional ability that distinguishes human beings from all other species.

- Finally, an administrative, civil rights complaint currently is pending that seeks the mandatory withdrawal of the existing AAC device guidance based on disability discrimination. The guidance offers unequal access to Medicare benefits to individuals who file Medicare claims for AAC devices because they must appeal to an administrative law judge before there is any substantive review of whether an AAC device is 'covered' or is 'reasonable and necessary.' All substantive review by Medicare decision makers below the ALJ level of review is precluded by the existing AAC device guidance. By contrast, other Medicare beneficiaries, with the same speech disabilities but at a lower level of severity, and other Medicare beneficiaries who require other types of speech-related devices, are able to obtain substantive review of their claims at every level of Medicare decision making.

For all of these reasons, it is appropriate for Medicare to re-review the existing AAC device guidance and to withdraw and replace it. Medicare should replace the existing guidance with professionally and programmatically sound guidance that will establish a national coverage standard for AAC devices.

IV. TYPES OF AAC DEVICES

A variety of AAC device designs/configurations exist because individuals with severe communication disabilities present a wide range of physical cognitive, linguistic, sensory, and motor deficits, as well as different daily communication needs. As a practical matter, no single device can offer the number of features required to enable all individuals with AAC device needs to achieve effective and efficient communication. To address the varied needs of individuals with severe communication disabilities, AAC devices are divided into three technologically and clinically distinct categories:

1. AAC devices with digitized speech output;

2. AAC devices with synthesized speech output, which require message formulation by spelling and device access by physical contact direct selection techniques; and

3. AAC devices with synthesized speech output, which permit multiple methods of message formulation and multiple methods of device access.

The key distinguishing features among the categories of AAC devices are the type of speech output (which may be either 'digitized' or 'synthesized') and, among synthesized speech output devices, the methods of message generation and device access. These design characteristics of AAC devices make each category of devices unique technologically and clinically, in that each offers features that can be matched by use of distinct clinical indicators to individuals' profiles of physical, cognitive, linguistic, sensory and motor deficits, and to individuals' communication needs.

A. CATEGORY # 1: AAC DEVICES WITH DIGITIZED SPEECH OUTPUT

'Whole message' or digitized speech output AAC devices are needed by individuals with cognitive and/or language impairments, which cause them to be unable to generate messages through spelling and/or by word-by-word development of their messages, such as those with severe aphasia due to cortical stroke. Digitized speech output is essentially natural speech -- of an individual other than the AAC device user, such as a spouse, SLP, or other person selected by the user -- that has been recorded, stored, and reproduced. AAC devices with digitized speech output are recognized in the professional literature as 'closed' systems because they reproduce only those words or messages that have been pre-stored for their user. Digitized speech devices also are called 'whole message' systems because they provide the user with an entire phrase, sentence, or message that can be accessed by a single selection on the AAC device. Examples of AAC devices with digitized speech output are shown in FIGURE 2. (A complete list of AAC devices with digitized speech output is found in **TABLES 8-11** in Section 5.)

As shown in FIGURE 5, among the category of AAC devices with digitized speech output are those with dynamic displays (*e.g.*, Dynamo) and static displays (*e.g.*, Message Mate, Macaw, Digivox), and devices that can be accessed with the use of accessories (access technologies) that offer different selection techniques such as physical contact direct selection, direct selection with an electronic accessory, or switch controlled indirect selection (*e.g.*, scanning or Morse Code). Although AAC devices with digitized speech output require messages to be pre-stored, the amount of language (words, phrases, sentences or messages) that can be stored in the device, and thus be available to the user, varies greatly. In addition, the memory capacity of AAC devices with digitized speech output ranges from devices that offer a minute or two of speech, to devices that can store an hour or more of speech.

B. CATEGORY # 2: AAC DEVICES WITH SYNTHESIZED SPEECH OUTPUT, WHICH REQUIRE MESSAGE FORMULATION BY SPELLING AND DEVICE ACCESS BY PHYSICAL CONTACT DIRECT SELECTION TECHNIQUES

Individuals who have the cognitive and linguistic ability to formulate messages independently require AAC devices with synthesized speech output. Speech synthesis is a technology that transfers text input into device-generated speech using algorithms representing linguistic rules, including rules for pronunciation, pronunciation exceptions, voice inflections, and accents of the language. Stated another way, synthesized speech AAC devices 'translate' the user's input into speech. Thus, unlike AAC devices with digitized speech output, there is no pre-recording of specific words, phrases, sentences, or messages by another person, and there is no time-limit or message length limit to the speech that can be produced. This characteristic leads synthesized speech AAC devices to be described as offering 'generative speech capability' or as being 'open systems' because users can construct original messages as their communication needs dictate.

During the clinical decision making process, once the determination is made that an individual requires a synthesized speech AAC device, the focus of the inquiry turns to identifying the individual's most effective and efficient methods of formulating messages and accessing the device. The SLP must match the user's linguistic skills to the message formulation, storage, and retrieval features available in a particular AAC device and match the user's access-related physical abilities and limitations to the access capabilities of the device.

Synthesized speech AAC devices in this category permit individuals to construct messages only by spelling and the use of physical contact direct selection techniques, such as use of a finger, hand-held stylus, head-stick, or mouth-stick. Devices in this category have a keyboard for message formulation and do not offer users alternative methods of access. They do not have extensive language storage or rate enhancement features that would support their users' ability to construct, store, and retrieve lengthy messages. FIGURE 3 provides examples of AAC devices with synthesized speech output that require message formulation by spelling and access by physical contact direct selection.

The AAC devices in this category are appropriate for individuals whose communication needs do not require production of lengthy messages, who can spell sufficiently well to generate their messages, and who will be able to make direct contact with the keyboard. An example is a person with ALS or cerebral palsy, who does not have very extensive communication needs and who has lost the ability to speak but who is a good speller and retains fine motor dexterity.

C. CATEGORY # 3: AAC DEVICES WITH SYNTHESIZED SPEECH OUTPUT, WHICH PERMIT MULTIPLE METHODS OF MESSAGE FORMULATION AND MULTIPLE METHODS OF DEVICE ACCESS

This category of synthesized speech AAC devices permits multiple methods of message formulation and access and allows users to take advantage of text, words, and/or pictographic symbols to formulate some messages or parts of messages and to spell others. AAC devices in this category also aid individuals who are non-literate but who have the cognitive and linguistic abilities to generate messages independently. Finally, they permit an individual to store and retrieve efficiently a large number of lengthy messages.

By offering multiple access methods, this category of synthesized speech devices can be used by individuals with a very wide range of physical limitations. Individuals can access the devices by physical contact direct selection, but if that is not an effective or efficient means of access, due to quadriplegia or locked-in-syndrome, for example, individuals can use an electronic accessory, such as a head mouse, optical head pointer, light pointer, infra-red pointer, eye-gaze, or joystick. If none of those accessories is appropriate, the devices in this category also will support access by indirect selection methods, such as switch-based scanning techniques and Morse code. As shown in FIGURE 5, this category of AAC devices consists of devices that have dynamic displays, for which the Editorial Panel awarded HCPCS code, E 1900, on October 28, 1999, and devices that have static displays.

D. AAC ACCESSORIES

AAC accessories support effective and efficient access to and proper positioning of an AAC device, safety during transport, and adequate power supply to meet an individual's communication needs throughout the day. AAC accessories also include specific AAC software that enable caregivers to more efficiently create new overlays to facilitate communication of new messages, and for some individuals, who have access to specially adapted laptop or desktop computers, (with a speech synthesizer, adequate speakers, sufficient power, and access aids) to use these devices as AAC devices.

An SLP will recommend AAC device accessories only when the individual is not capable of effectively or efficiently using the device without these adaptations. For some individuals, such as those with locked-in-syndrome and ALS, alternative methods of access are required because of the severe physical limitations imposed by these conditions. Other individuals may be able to make physical contact with the AAC device, but may not be able to generate sufficient force to consistently operate the keys, thus increasing the number of errors in construction of their messages, the time and energy required to construct messages, and the frustration associated with communicating, all of which decrease the effectiveness and efficiency of communication.

Three types of alternative access accessories exist: accessories that are non-electronic and support direct selection; electronic aids that support direct selection; and switches that facilitate indirect selection techniques. **TABLE 14** identifies examples of AAC device accessories in each of these categories. When considering any AAC accessories, the goal is to match the user's physical abilities and limitations with the accessory most likely to allow the individual to achieve effective and efficient communication with the AAC device. The assessment process related to AAC accessories is sequential. The simplest solutions, *i.e.*, the non-electronic aids for direct selection, are considered first. If the individual does not have the hand, arm, or head control required for these aids, consideration is then given to the electronic direct selection aids. Finally, if neither direct selection technique will enable the individual to use the AAC device effectively and efficiently, consideration is given to switch-operated, indirect selection techniques (*e.g.*, scanning, Morse Code).

V. PROPOSED NATIONAL COVERAGE DECISION

Stated below is the text of a proposed National Coverage Decision for AAC Devices. In addition, Appendix I, Tab C, lists the names, addresses and other contact information for a group of AAC professionals who have volunteered to provide advice and counsel to HCFA, the DMERC medical directors, and other Medicare decision makers regarding AAC device claims.

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, apraxia of speech, or aphasia, 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 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 xxx1 is covered if the patient meets:

a. criteria 1-3 but not

b. criteria 4, 5 and 6

Code E xxx2 is covered if the patient meets:

a. criteria 1-5 and 7 but not

b. criteria 6, 8, and 9

Code E xxx3 is covered if the patient meets:

a. criteria 1-3 and

b. criteria 4 and 6

Clinical Criteria:

1. The individual has a communication disability with a diagnosis of severe dysarthria, apraxia, and/or aphasia.
2. The individual's communication needs that arise in the course of current and projected daily activities cannot be met using natural communication methods.
3. The individual requires a speech output communication device to meet his/her functional communication goals.
4. The individual possesses the linguistic capability to formulate language (messages) independently.
5. The individual will produce messages most effectively and efficiently using spelling.
6. The individual will require an AAC device with extensive language storage capacity and rate enhancement features.

7. 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.

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

9. 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 patient must meet criteria 4 and 6 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 Exxx1.

VI. CONCLUSION

This Formal Request for an AAC Device National Coverage Decision provides the information HCFA staff identified in mid-August as necessary to permit review of the existing Medicare AAC device guidance. This Executive Summary and the detailed narrative sections and appendices that follow support AAC device classification by Medicare as frequently purchased DME. In addition, this Formal Request supports a determination by HCFA to withdraw and replace the existing AAC device guidance with the proposed National Coverage Decision that is enclosed.

As the HCFA review of this Formal Request proceeds, the AAC professionals who prepared these materials remain ready to respond to questions, participate in discussions, provide additional information, and otherwise facilitate HCFA staff's understanding of these materials and its determination to adopt the proposed AAC Device National Coverage.[2] For any additional information or assistance, Lewis Golinker, Esq., will serve as the point of contact. Lewis Golinker is the Director, Assistive Technology Law Center, 202 East State Street, Suite 507, Ithaca, New York 14850, tele: 607-277-7286(v); 607-277-5239(fax); lgolinker@aol.com (e-mail).

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2 Given the wealth of technical information provided in this Formal Request, the numerous professionals available for clarification, as well as past assurances by HCFA staff that further review would be unnecessary, we submit that HCFA can adopt the proposed NCD without referring it to the Medicare Coverage Advisory Committee (MCAC) or undertaking a technology assessment to review the findings presented.

VII. ORGANIZATIONS AND INDIVIDUALS INVOLVED WITH PREPARATION OF THIS REQUEST

In June 1999, HCFA staff provided notice that Medicare was prepared to review its non-coverage policy for AAC devices and requested that concerned parties submit information to assist with that task. This Formal Request for an AAC Device National Coverage Decision was prepared by the nation's leading AAC professionals, identified below in Section A, and it is submitted on behalf of the thirteen organizations identified below in Section B. These organizations represent the interests of Medicare beneficiaries, assessment and treatment professionals, AAC device manufacturers, and other advocates for those with speech impairments. All of these organizations and the individuals they serve have direct interests in the reversal of HCFA's non-coverage policy. This Formal Request provides the information and analyses that HCFA staff has requested and which will permit the expeditious decision to withdraw and replace the existing Medicare AAC device guidance with a set of professionally sound coverage criteria.

A. AAC PROFESSIONALS WHO PREPARED THIS FORMAL REQUEST[3]

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2. Sarah W. Blackstone, Ph.D., President, Augmentative Communication, Inc., Monterey, California.

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4. Kevin Caves, B.S.M.E., Director, Rehabilitation Engineering Research Center on Communication Enhancement, Clinical Associate, Department of Surgery, Duke University Medical Center, Durham, North Carolina.

5. Frank DeRuyter, Ph.D., Chief, Division of Speech Pathology and Audiology, Department of Surgery, Duke University Medical Center, Durham, North Carolina.

6. Lynn E. Fox, Ph.D., Assistant Professor, Speech and Hearing Sciences Program, Portland State University, Portland, Oregon.

7. Carol M. Frattali, Ph.D., Research Coordinator, Speech-Language Pathology Section, National Institutes of Health, Bethesda, Maryland.

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3 The Curiculum Vitae of these AAC Professionals are attached in Appendix I at Tab A.

8. Kathryn L. Garrett, Ph.D., Assistant Professor, Department of Speech-Language Pathology, Duquesne University, Pittsburgh, Pennsylvania.

9. Audrey L. Holland, Ph.D., Regents' Professor of Speech & Hearing Sciences, Department of Speech & Hearing Sciences, University of Arizona, Tuscon, Arizona.

10. Pamela A. Mathy, Ph.D., Clinical Professor and Director of Clinical Services, Speech and Hearing Clinic, Arizona State University, Tempe, Arizona.

11. Patricia R. Ourand, M.S., C.C.C.-S.L.P., Associated Speech & Hearing Services, Baltimore, Maryland.

12. Maggie Sauer, M.S., C.C.C.-S.L.P., Research Assistant Professor, Department of Medical Allied Health Professions, University of North Carolina, Chapel Hill, North Carolina.

13. Howard C. Shane, Ph.D., Director, Communication Enhancement Center and Speech and Language Services, Children's Hospital, Boston, Massachusetts, and Associate Professor, Harvard Medical School, Cambridge, Massachusetts.

14. Kathryn M. Yorkston, Ph.D., Professor, Rehabilitation Medicine, University of Washington, Seattle, Washington.

B. Organizations Submitting This Formal Request[4]

1. American Speech-Language-Hearing Association
2. Amyotrophic Lateral Sclerosis Association
3. Brain Injury Association
4. Center on Disability and Health
5. Communication Aid Manufacturers Association
6. Communication Independence for the Neurologically Impaired
7. International Society for Augmentative & Alternative Communication
8. National Association of Protection & Advocacy Systems
9. National Multiple Sclerosis Society

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4 A description of each organization is attached in Appendix I at Tab B.

10. RESNA

11. Sunrise Medical

12. United Cerebral Palsy Associations

13. United States Society for Augmentative & Alternative Communication

SECTION 3: CLINICAL ASPECTS OF AAC DEVICES

OVERVIEW

Subpart I of this section discusses the characteristics and treatment of severe dysarthria, apraxia, and aphasia, the medical conditions most closely associated with the need for AAC interventions. Subpart II discusses the clinical decision making process by which the need for specific AAC devices is determined. It delineates the process that SLPs undertake in ascertaining the need for AAC treatment, *i.e.*, whether an AAC device is required and, if so, which device will enable the individual to meet the treatment goals specified in his or her treatment plan. In addition, this section describes the nine key clinical indicators used to determine the specific category of AAC devices and the specific AAC device and accessories that are appropriate for an individual. The decision making process is outlined in outlined in **FIGURE 1**. These clinical indicators and relationship with device categories are identified in **TABLE 4**. The narrative report is then sent to the beneficiary's treating physician. The physician is responsible for prescribing AAC treatment and completing the certificate of medical necessity.

I. MEDICAL CONDITIONS ASSOCIATED WITH NEED FOR AAC DEVICES

AAC devices generally are recognized as appropriate treatment for, and have become standard practice in, the treatment of individuals with severe dysarthria, apraxia, and aphasia. These speech (dysarthria, apraxia) and language (aphasia) impairments are associated with a variety of neurologic conditions, the most common including amyotrophic lateral sclerosis (also known as ALS or Lou Gehrig's Disease), cerebral palsy, locked-in-syndrome, multiple sclerosis, Parkinson disease, brain-stem stroke, cortical stroke, progressive aphasia, and traumatic brain injury. Each of these conditions can adversely affect the ability of individuals to communicate during the course of daily activities. When these conditions are severe, the preferred treatment in speech-language pathology is utilizing an AAC device. One important approach to AAC treatment is the use of speech output communication devices, which can enable an individual who is unable to produce intelligible speech to 'speak' using machine-generated synthetic speech. Thus, for some individuals with these conditions, AAC devices provide the primary means to overcome severe speech and language impairments and thereby to communicate effectively.

Dysarthria, apraxia and aphasia are speech and language impairments that each adversely affects the speech production process. The 'communication chain' model describes speech production as a sequential process involving five distinct physical structures and functions that are inter-connected like links of a chain (Crystal and Valley, 1999). Dysarthria, apraxia and aphasia each 'breaks' a different link of the communication chain, adversely affecting the ability to communicate by using speech.

The communication chain begins with an idea or thought, which occurs within the memory storage structures of the brain. The formulation of an idea or thought is called the 'pre-linguistic link.' It suggests that thoughts and ideas exist independently of language (Pinker, 1994).

A second, separate link gives the idea a linguistic shape. 'Language' or 'linguistic' encoding is the second link in the communication chain. These involve pragmatic (communicative intent), semantic (meaning), syntactic (word order), and phonological (sound) processing, transforming an idea into the substantive message to be communicated. When the linguistic encoding process is completed, the message is fully specified in terms of its communicative intent, its meaning, its word order, and its sound.

The third link is motor programming, which converts the linguistically encoded message into a form that can be conveyed to some external receiver, such as the ear of a communication partner. Motor programming takes the linguistic message and converts it to a set of instructions used to command the muscles used in speech. Motor programming can be compared to a software program which contains the operating instructions for the hardware (the vocal organs and associated nerves) required for speech production.

Once the message is programmed for speech production, the fourth link of the chain, the motor execution system, is activated to implement the program. The motor system is comprised of the motor areas of the brain and nerves which run from the brain to the muscles of the speech mechanism. The system also includes a network of nerves that provides feedback to the brain to ensure the motor instructions are being executed correctly, and as needed, to modify the instructions.

Finally, the fifth link in the chain is speech production, which is the result of the integrated functioning of three sub-systems: respiration, phonation, and articulation. The respiratory system provides the power source for speech. The movements of the muscles inside the chest cavity force air either into or out of the lungs. The phonatory component of speech involves the action (vibration) of the vocal folds within the larynx. The vibration or non-vibration of the vocal folds, as well as their length affect pitch, loudness, tone of voice, as well as the ability to produce particular sounds. The articulatory component of speech production involves various structures within the mouth, including the tongue, lips, palate, and teeth. The airstream, set in motion by the action of the lungs and chest muscles, and which may or may not have vibration super-imposed on it by the action of the larynx, is shaped by the various articulatory structures to produce the different sounds of speech. To produce intelligible speech, each link of the communication chain must be working properly, in a finely controlled sequence, and in a very short span of time.

Dysarthria, apraxia, and aphasia, the conditions that give rise to AAC intervention needs, 'break' different links of the communication chain. Aphasia is a disorder affecting the first two links: those involved in the formulation of meaningful expressions. Apraxia is a disorder of the third link: the retrieval and implementation of an articulatory program (motor programming). Dysarthria is an impairment to the fourth and fifth links: the subsequent action of the speech production system to give linguistic units phonetic reality (motor execution and speech production). In some individuals, only one link of the chain is disrupted. In many others, however, more than one link is affected by the individual's primary disease or condition. The characteristics of each of the conditions requiring AAC interventions are discussed more fully below.

A. CHARACTERISTICS OF SPEECH-LANGUAGE IMPAIRMENTS REQUIRING AAC TREATMENT: DYSARTHRIA

The dysarthrias refer to a widely varying group of motor speech disorders associated with many neurologic conditions (ALS, multiple sclerosis, Parkinson disease). The perceptual and physiologic characteristics of the dysarthrias are well described, and a variety of treatments that increase the intelligibility and naturalness of speech are now part of standard practice in speech-language pathology. For some individuals with severe dysarthria, regaining use of natural speech to meet communication needs in daily living is not a realistic goal of intervention. For this small number of individuals, AAC intervention is the most efficacious treatment focus.

Dysarthria is a collective term used to describe a group of speech disorders caused by disturbances in muscular control resulting from damage to the central and/or peripheral nervous system (Darley, Aronson, & Brown, 1975; Duffy, 1995; McNeil, 1997; Yorkston, Beukelman, Strand, & Bell, 1999). Depending on the location of the central and/or peripheral nerve damage, an individual may manifest a variety of motor impairments including weakness, slowness, incoordination, or altered muscle tone, which in turn disrupt the respiration, phonation, articulation, resonance, and prosody required for intelligible speech. By definition, dysarthria does not affect receptive communication abilities (the ability to understand what is spoken or written). The effects of dysarthria on speech production can range from mild speech production problems to a complete inability to speak intelligibly or even to make guttural sounds, a condition known as anarthria. Dysarthria and anarthria occur in both children and adults. The condition can be stable, improving, or degenerative.

The prevalence of dysarthria in the United States must be extrapolated from demographic data detailing the incidence of neuromuscular diseases associated with dysarthria, such as cerebral palsy, Parkinson disease, amyotrophic lateral sclerosis (ALS), traumatic brain injury, brain-stem stroke, and later stages of multiple sclerosis, because dysarthria often is a symptom of these diseases/conditions. TABLE 1 offers an overview of each, depicting the typical course, age of onset, symptoms and prevalence of dysarthria among people with the disease or condition. It should be noted, however, that dysarthria also may arise from other diseases with neurologic sequelae, including tumor, postoperative complications, inflammatory and metabolic diseases, and other sporadic degenerative neurology conditions (Yorkston *et al*, 1999).

TABLE 1: DISEASES AND CONDITIONS ASSOCIATED WITH SEVERE DYSARTHRIA[5]

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Cerebral palsy	Stable	Congenital	Spasticity, flaccidity, ataxia, and/or dyskinesia	31% to 88%
Amyotrophic Lateral Sclerosis	Rapidly progressive	Mean age of onset mid-50's	Degeneration of motor neurons. Symptoms depend upon the course of disease	75% of patients are unable to speak at time of death
Multiple Sclerosis	Slowly progressive	Between 18 - 40 years of age	Variable depending on the size, age, activity, location of CNS lesions	40% to 44% report speech affected; Less than 20% report severe dysarthria
Parkinson Disease	Slowly progressive.	Mean age 55 years	Resting tremor, rigidity, paucity of movement, impaired postural reflexes, dysarthria	22% - moderate dysarthria. 29% - severe dysarthria
Brain-stem Stroke	Improving with later stabilization	Age 45-64: 998 per 100,000 Age 65+: 5,063 per 100,000	Variable depending on the site of lesion and amount of damage to the central nervous system	Severe dysarthria to anarthria for individuals with 'locked-in syndrome
Traumatic Brain Injury	Improving with later stabilization	Bimodal population. Peaks at ages 15-24 and 65-75	Variable depending on nature of injury	60% in acute rehab setting to approximately 10% long-term post-onset

5 Adapted in part from Yorkston, et al (1999).

1. AAC Devices As Treatment For Dysarthria

Whether AAC treatment is recommended for someone with dysarthria depends upon the severity of their speech impairment and the projected course of their disease or condition. An SLP determines individual need through a motor speech assessment consisting of five parts including a case history, the examination of the oral mechanism during nonspeech activities, assessment of perceptual speech characteristics, assessment of intelligibility, and acoustic physiologic analyses (Duffy, 1995). Typically, an SLP uses a severity-based classification system as a guide for selecting an appropriate treatment for dysarthria. Staging is a term common in medical practice that creates classifications for the purpose of identifying appropriate and effective interventions for different severity levels of a disorder. **TABLE 2** summarizes five stages of severity for the dysarthrias. Based on several factors, including the natural course of the disease or condition and the severity of the speech disorder, clinicians can determine when (and what type of) AAC treatment is necessary. (Yorkston *et al*, 1999).

As noted below, Stages I, II, and III require techniques that focus on strengthening the speech musculature and improving articulation, voicing, and overall intelligibility. For individuals with severe dysarthria or (Stages IV or V), AAC intervention is recognized as the most effective course of treatment (National Joint Committee on the Communicative Needs of Persons with Severe Disabilities (1992)). At Stage IV, AAC treatments often include no-tech and low-tech techniques. In addition, AAC devices may be recommended for use in social and community contexts, for telephone use, and with unfamiliar partners. At Stage V, when speech is no longer functional, most individuals with dysarthria require the use of electronic AAC devices and other accessories to enable them to communicate effectively.

TABLE 2: STAGES OF SEVERITY FOR DYSARTHRIA

	DESCRIPTION	TREATMENT APPROACHES
Stage I	No detectable speech disorder	Educate the patient, family, and caregivers regarding the course of the disease and future communication needs and options.
Stage II	Obvious speech disorder with intelligible speech	Reduce the impairment through strengthening muscles related to speech production and range of motion exercises.
Stage III	Reduction in speech intelligibility	Same as above. In addition, introduce to the speaker and listeners to strategies that improve intelligibility (slower rate of speech, first-letter cueing).
Stage IV	Residual natural speech and AAC	Supplement natural speech and teach compensatory strategies to individual and their partners. Introduce AAC treatment, such as an AAC device.
Stage V	Loss of useful speech	Provide a multi-purpose AAC device and accessories as well as non-electronic (back up) strategies.

After determining the need for AAC treatment, the SLP, often in collaboration with other allied health professionals, continues the assessment process in order to identify the specific type of AAC treatment required and type of device and accessories needed. Section II, below, contains additional information about the AAC decision making process, *i.e.*, how the SLP considers these data in making a recommendation for an AAC device.

Individuals with severe dysarthria often employ a variety of AAC techniques to improve or restore their ability to communicate. Treatment may include non-electronic communication aids (*e.g.*, alphabet boards) and electronic devices that provide speech output. The purpose of AAC treatment is to establish effective independent communicative capabilities so that the person with severe dysarthria can meet the communication needs that arise in the course of daily activities (Beukelman *et al.*, 1985; Beukelman & Mirenda, 1998; Kearns & Simmons, 1988; Rosenbek & LaPointe, 1985; Beukelman & Yorkston, 1977). The characteristics of common conditions or diseases that cause dysarthria and the treatment effectiveness of AAC devices are described below.

a. Use of AAC Devices for Common Conditions or Diseases Causing Dysarthria

Amyotrophic Lateral Sclerosis. Amyotrophic lateral sclerosis (ALS) is a rapidly progressive neurological disease involving the motor neurons of the cortex, brainstem, and spinal cord. The classical picture of ALS is one of motor loss with preserved sensation and cognition. AAC treatment, including the use of AAC devices, has long been a part of management of this disease (Adams, 1966; Kazandjian, 1997; Yorkston, Miller & Strand, 1995). At the ALS Standard of Care Consensus Conference, AAC intervention was recognized as the standard of care for treatment of the communication impairments associated with ALS. (R. Sufit, 1997).

A number of studies demonstrate that AAC devices are an effective treatment for the communication problems experienced by individuals with ALS. In a cross sectional study of 110 individuals with ALS seen in an outpatient clinic, Yorkston and her colleagues identified six groups of people with ALS based on speech, upper extremity and lower extremity functioning. Each group presented with a different set of symptoms affecting communication (speech and writing), given the course of the disease process. According to the study, Group 1 (45%) was comprised of individuals who had both adequate speech and upper extremity function; thus, management involved monitoring for potential deterioration. Group 2 (20%) included individuals with adequate speech but poor hand function. This group required assistive technology for written communication. Group 3 (16%) included individuals with severe dysarthria who had adequate hand function and mobility. This group often used handwriting for face-to-face communication but required AAC devices when interacting in groups and to talk on the telephone. In consideration of the progressive nature of the disease process, AAC devices with a range of access options (direct selection, scanning) were recommended for individuals in this group. Individuals in Group 4 (10%) had insufficient speech, adequate hand function, and were non-ambulatory. They used handwriting, direct selection AAC devices (low and high tech), typewriters, and computers. Equipment was mounted on wheelchairs and beds, or placed on tables. Group 5 (2%) included individuals who had severe dysarthria, poor hand function, and good mobility. These individuals required lightweight, portable AAC devices with features that included alternate access modes. Finally, Group 6 (7%) had severe dysarthria, poor hand function, and poor mobility. This group often required AAC devices that enabled them to use switches and scanning techniques for access. Over the course of the disease process, it is typical for individuals to move from Group 1 to other groups. (Yorkston, Strand, Miller, Hillel, & Smith, 1993).

Parkinson Disease. Parkinson disease is a relatively common slowly progressive disease of the central nervous system, especially the basal ganglia. Although speech disorders typically do not occur early in the disease, as the disorder progresses, about two thirds of individuals with Parkinson disease have reported changes in speech, rate, and voice. (Hartelius & Svensson, 1994). Simple, non-electronic AAC systems have a long history of successful use with this population (Beukelman & Mirenda, 1998; Helm, 1979; Lang 1983; Yorkston, Beukelman, Strand & Bell, 1999). Delayed Auditory Feedback stategies are sometimes effective in slowing speaking rates and improving intelligibility while preserving the naturalness of speech. (Adams, 1966). Only a small minority of these individuals require speech output AAC devices.

Multiple Sclerosis. Multiple sclerosis (MS) is a demyelinating disease of the central nervous system most typically diagnosed in young adults, ages 18 to 40 years (Yorkston, Miller & Strand, 1995). The two most common forms of MS are relapsing-remitting (approximately 40% of cases) and chronic progressive (20% - 30% of cases). It has been estimated that there are 250,000 to 500,000 cases of MS in the United States (Scheinberg & Smith, (1987). Approximately 40% of all patients with MS experience dysarthria which typically presents as spastic-ataxic dysarthria along with reductions in voice intensity and disturbances in vocal quality (Merson & Rolnick, 1998). In a survey of 460 patients with Parkinson disease or MS, Hartelius and Svensson (1994) found that 44% of the MS patients had experienced impairment of speech and voice after the onset of their disease. Their speech disorder was considered one of their greatest problems by 16% of the patients with MS, however only 2% of the patients surveyed had received any speech intervention.

Locked-in-Syndrome. The term 'locked-in syndrome' is used to describe a condition in which the patient is mute but consciousness may be preserved, and the only volitional motor activity is vertical eye movements and blinking. It is usually of vascular origin with the majority of cases experiencing a brainstem infarct or hemorrhage (Haig, Katz, & Sahgal, 1987; Patterson & Grabois, 1986). Initially, only simple blink systems to indicate yes/no or to generate messages using Morse code were reported (Feldman, 1971; Gallo & Fonanarosa, 1989; Gauger, 1980; Kenny & Luke, 1989). For example, Jean Dominique Bauby, who had been the editor of *Elle* magazine in France, and who developed locked in syndrome following a stroke, wrote a best selling memoir, *The Diving Bell and the Butterfly* (1997) that described his condition. The title of this book is itself a metaphor for locked-in-syndrome: the body, trapped in a diving bell, while the mind and the imagination, can still soar like a butterfly. Bauby's book was written using a non-electronic eye-blink process. 'Its a simple enough system. You read the alphabet . . . until with a blink of my eye, I stop you at the letter to be noted. The maneuver is repeated for the letters that follow . . . [until] you have a whole word, and then fragments of more or less intelligible sentences.' Despite its laboriousness, Bauby was clear in his gratitude for having even this crude means of communication. He wrote: 'The identity badge pinned to Sandrine's white tunic says 'Speech Therapist,' but it should read 'Guardian Angel.' She was the one who set up the communication code without which I would be cut off from the world.' (Bauby, 1997).

In patients with incomplete locked-in syndrome, alphabet boards have been documented as effective in supplementing natural speech (Beukelman & Yorkston, 1977). As more technology is becoming available, personal testimonies of people with locked-in-syndrome utilizing AAC devices are appearing in the mainstream literature. For example, Julia Tavalaro's book '*If you want to talk with me, I look up for Yes,*' chronicles her experience of being considered 'brain-dead' for six years after a brain stem stroke, during which she was paralyzed without a way to communicate. She says, 'No one knows how dark the night is until you can't speak into it.' (Tavalaro & Tyson, 1997). Thirty years later, Ms. Tavalaro is publishing her poems and communicating with family and friends from her residence on Roosevelt Island, New York. Another example is an engineer who experienced a brainstem stroke in his mid 50s. Even after he had regained some natural speech he commented about his AAC device: 'I only used one finger to touch any key but it was, and even today, still is at times, a 'sanity saver' to me! . . . I can only too well envisage my world without this little 'workhorse.'' (Montgomery, 1991, p.75).

Traumatic Brain Injury. Traumatic brain injury (TBI) occurs most frequently as a result of a motor vehicle accident or a fall. Injuries to the head that result in temporary or permanent brain damage are quite common, however, only about one-third of those with TBI ever experience dysarthria, and only a small proportion of those require AAC devices (Sarno, 1986). As in many other populations, simple non-electronic AAC techniques were the first to be reported (Beukelman & Yorkston, 1977; Keenan & Barnhart, 1993).

Issues related to the AAC management of individuals with TBI are complex (DeRuyter & Becker, 1988; DeRuyter & Kennedy, 1991; DeRuyter & LaFountaine, 1987). Cognitive limitations during early phases of recovery make the operation of complex AAC devices difficult for many. Changing cognitive and motor performance may make selection of an appropriate long-term AAC system ill-advised until later in the recovery process. Thus, the focus of intervention has shifted from providing single long-term AAC devices to providing a series of AAC techniques designed to meet current communication needs. These transitions are illustrated in a case report of an adolescent with TBI followed for 3 years, initially to establish a yes/no system, later to use an electronic AAC device, and finally to re-establish natural speech (Light, Beesley & Collier, 1988). Other successful interventions are reported in complex cases wherein cognitive issues are challenging. (DeRuyter & Donoghue, 1989).

Cerebral Palsy. Cerebral palsy refers to a developmental neuromotor disorder that is the result of a non-progressive abnormality of the developing brain. Dysarthria is common. Several types of motor problems may be present depending on the location of the brain lesion. Associated disorders are also common, including cognitive impairment, vision problems, hearing impairments, and seizure activity. (Beukelman & Mirenda, 1998). Although prevalence statistics for adults are difficult to obtain, studies suggest that the majority of the most severely affected individuals survive to adulthood. (Evans, Evans & Alberman, 1990). AAC interventions, including use of electronic devices, have long been recognized as appropriate for individuals with cerebral palsy. Research related to the use of AAC interventions by individuals with cerebral palsy as well as individual case studies are discussed in sub-section b ('stable (improving) conditions') below.

b. Efficacy of AAC Devices as Treatment for the Dysarthrias

Researchers are beginning to document the efficacy of AAC intervention with individuals who have severe speech disorders resulting from dysarthria. Examples of the results are summarized below. The results to date indicate that AAC intervention has a profound impact on the ability of individuals with dysarthria to meet their communication needs in the course of their daily lives. The first section will focus on studies of AAC intervention with individuals who have progressive conditions (ALS, MS, Parkinson) and the next section will focus on static or improving conditions (TBI, locked-in syndrome, cerebral palsy).

Progressive (degenerating) conditions. The most research to date has been done with ALS because it results in the largest proportion of individuals who are unable to speak at some point during the disease process. For example, in a retrospective chart review of treatment data for 126 persons with ALS (61 males; 65 females), Guttman and Gryfe, (1999) found that, 72% of the men and 73% of the women had begun AAC treatment. There were clear patterns of preferences, by gender, with respect to the type and nature of augmentative intervention received. Women preferred speech output systems almost twice as often as did men (49% of women; 26% of men). Women used low tech options (alphabet boards) almost three times as often as men (20% of women; 6% of men). Men chose high tech AAC devices with extensive language storage capacity that could support written communication and spoken communication almost three times more often than did women (34.9% of men; 12.1% of women). These data suggest gender differences in the use of AAC devices among people with ALS.

Studies of user satisfaction for individuals with ALS also are becoming available (Mathy, Yorkston & Gutmann, in press). Based on interviews using in-depth rating scales, individuals with ALS reported generally high levels of satisfaction (ratings ranging from 5 to 7 on a 1 to 7 scale with 1 being the least satisfied and 7 being the most satisfied) with their AAC devices in meeting their daily communication needs. Individuals expressed the highest level of satisfaction with devices that provided extensive language storage that supported the ability to create, store and retrieve lengthy messages pertaining to needs/wants, and sharing information with their family and care providers. Subjects were less satisfied (average rating 4) with their high tech AAC devices for conversation. Because conversation is a rapid exchange of ideas, opinions, etc. between at least two people, it is likely that subjects' poorer evaluation of their augmentative communication methods for use in conversation reflects the reduced message construction rate imposed by their severe motor impairments.

Beukelman, Kraft and Freal (1985) surveyed 656 persons with a diagnosis of MS regarding the presence of expressive communication disorders and the frequency of use of AAC devices. They found that 23% of those surveyed reported the presence of speech deficits with 4% of the sample indicating that their speech disability was so severe that strangers could not understand them. Of the group reporting severe speech impairments, 28.8% indicated that they used an augmentative communication device.[6]

Stable (improving) conditions. Reports of individuals with locked-in syndrome followed longitudinally have noted progress from individual communication based on minimal eye movement to successful use of computerized AAC devices (McGann & Paslawki, 1991; Simpson, Till & Goff, 1988). Culp and Ladtkow (1992) followed a series of 16 individuals with locked-in syndrome for at least 1 year to document their AAC needs. At follow-up, half were able to use direct selection to access communication devices and half relied on visual or auditory scanning techniques. Only 20% of cases in this study chose not to pursue electronic communication options.

Longitudinal research tracking the AAC needs of individuals with TBI has been reported. Ladtkow and Culp (1992) followed 132 individuals with TBI over an 18-month period. Approximately 20% were judged to be 'non-speaking' at some point in their recovery. Of these individuals, 55 % regained function speech while the remainder did not. Although dysarthria generally resolves during the early and middle stages of recovery, severe motor speech deficit may persist (Dongilli, Hakel, & Beukelman, 1992). The implication of these findings is that for a small number of individuals with TBI, the need for AAC devices may extend over long periods of time. AAC use is critical, because it allows individuals with TBI to participate effectively in their rehabilitation programs as well as meet their ongoing communication needs.

Studies of the AAC needs of individuals with cerebral palsy also are available. In a survey of 66 non-speaking clients with cerebral palsy, the majority used simple augmentative communication systems (57.5%) and accessed them through direct selection in 62% of the cases (LaFontaine & DeRuyter, 1987). Research into the effectiveness of AAC devices has focused on the features of the systems, particularly identifying those features that are most beneficial. For example, Angelo (1992) compared three different scanning modes and found that individuals with different types of cerebral palsy benefited from different scanning modes. Light and Lindsay (1992) studied message-encoding strategies and found that letter-encoding resulted in more accurate learning than iconic techniques. McNaughton and Tawny (1993) studied two different spelling strategies and found that although learning rates were the same, one technique showed a retention advantage.

Treatment studies focusing on learning to use AAC devices have recently received considerable attention. Learning has been documented in groups of individuals (Udwin & Yule, 1990, 1991a & b), single-case research designs (Dattilo & Camerata, 1991; Glennen & Calculator, 1985), and case reports (Ferrier, 1991, Goossens, 1989; Spiegel, Benjamin & Siegel, 1993). Outcomes are documented using a variety of parameters, including conversational

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6 In addition to research studies, case examples of the effectiveness of AAC devices for people with ALS abound in the literature and now, over the internet, including information about the physicist and author Stephen Hawking and many others (*e.g.*, Doug Eshleman, http://www.lougehrigsdisease.net).

participation (Dattilo & Camarata, 1991), increased spontaneously initiated requests (Glennen & Calculator, 1985), and percentage of hours in the day that systems were used (Culp, Ambrosi & Berniger, 1986).

In addition, there are a plethora of case examples of individuals with cerebral palsy and severe dysarthria who use AAC devices effectively in their daily lives. Bob Williams, Rick Creech, Peg Johnson, Gus Estrella, Mick Joyce, Jennifer Lowe, Michael Williams, Gordon Richmond, and Bill Rush are some of the men and women ranging in ages from 20 to 65 who lecture and have written extensively about the impact of AAC devices on their lives. All are productive and highly respected members of their communities. They represent just a small sample of the growing number of individuals with cerebral palsy in the United States who use AAC devices effectively to do things they would otherwise not be able to accomplish.

c. Summary of Evidence Supporting the Effectiveness of AAC Devices in Severe Dysarthria

In summary, motor speech disorders such as severe dysarthria cause profound adverse effects on the ability to meet the communication needs that arise in the course of daily activities. The limitations associated with severe dysarthria have been described as causing 'not a loss of life, but a loss of access to life.' (Beukelman and Garrett, 1988). The inability to speak severely affects an individual's ability to maintain family roles, participate in family activities, and maintain personal independence. It also leads to significant isolation and precludes the very communication -- about home, family, health, and social matters -- that research recognizes is typical of older adults. (Stuart, Vanderhoof and Beukelman, 1993).

When working with adults with severe dysarthria, clinicians quickly begin to appreciate the fact that no one "wants" to use AAC devices. One woman with severe dysarthria associated with ALS told her clinician, 'You above all people should know that I'd rather be talking, but I must admit that this thing [the AAC device] is my lifeline to the world." This client's mixed feelings reflect both the extent of her loss and an appreciation of the importance of communication, albeit via technology. In sum, the evidence presented here supports the fact that carefully selected AAC devices are a reasonable, necessary, and effective treatment for individuals with severe dysarthria.

B. Characteristics Of Speech Language Impairment Requiring AAC Treatment: Apraxia Of Speech

Apraxia is a deficit in the third link of the communication chain, where planning and programming of the sequence of movements for speech occur. Acquired apraxia of speech is a speech disorder resulting from brain injury that is characterized by changes in articulatory features (*e.g.*,. multiple speech sound errors that occur inconsistently), movement characteristics (*e.g.*, groping for the correct articulatory posture), and disturbances in prosody (slow rate and unusual stress patterning). The most common cause of apraxia is stroke although it also may occur with brain damage resulting from a tumor or traumatic brain injury. In a recent neuro-imaging study of individuals with stroke with and without apraxia, a specific area of the brain was implicated. Individuals with apraxia had lesions that included a discrete region of the left precentral gyrus of the insula, a cortical area beneath the frontal and temporal lobes (Dronker, 1996). This area was completely spared in all individuals who did not exhibit apraxia. Recent literature also contains reports of individuals with primary progressive aphasia, a disorder of unknown etiology in which there is a history of isolated speech and language deterioration (Didic, Ceccaldi, & Poncet, 1998; Hart, Beach, & Taylor, 1997; Southwood & Chatterjee, 1998). Primary progressive aphasia is associated with apraxia of speech and non-fluent aphasia in approximately 30% of cases (Rogers & Alarcon, 1997). Many of these individuals progress to the point that they are unable to communicate without the assistance of AAC devices.

Evidence confirms that apraxia is a motor rather than linguistic deficit (Duffy, 1995; McNeil, Robin, & Schmidt, 1997; Yorkston, Beukelman, Strand, & Bell, 1999). This distinction is important because of its implication for planning treatment. Because of the specific nature of their deficits, it can be argued that individuals with apraxia should receive different types of treatment than individuals with aphasia (Tonkovich & Peach, 1989). For example, persons with apraxia in the absence of aphasia would be more likely to use spelling based AAC devices because their linguistic processing abilities are not affected. Whereas persons with apraxia and concomitant aphasia, may need devices that provide the ability to combine picture symbols to construct messages due to impairments in linguistic abilities (*i.e.*, spelling, syntax) associated with aphasia. It is important to determine the relative contribution of apraxia and aphasia and design treatment programs that fit the disorder (Yorkston *et al.*, 1999).

Apraxia rarely occurs as an isolated disorder. In other words, it co-occurs with aphasia, dysarthria, or both. In an early report (Wertz, 1985), apraxia was estimated to occur in isolation only approximately ten percent of the time, with aphasia 85 percent of the time and with dysarthria approximately 5 percent of the time. When apraxia is severe, it is nearly always is associated with aphasia. Thus, it is particularly important to note the co-occurrence of apraxia and aphasia because of the consequences for AAC intervention. Exact statistics about the prevalence of apraxia are not available. But because aphasia and apraxia typically co-occur, apraxia can be considered a subset of aphasia occurring in perhaps a quarter of cases with aphasia.

The past 30 years have seen remarkable progress in our understanding and treatment of apraxia/dyspraxia of speech. As a clinical entity, apraxia, has been defined and distinguished from aphasia and dysarthria. Understanding the nature of apraxia has allowed SLPs to develop more effective treatment programs to restore use of natural speech. At the same time, increased attention has been given to the treatment needs of those individuals with severe apraxia, for whom the return of natural speech is not possible. For these individuals, the professional literature confirms the effectiveness of AAC intervention in general and AAC devices in particular.

1. AAC Devices As Treatment For Apraxia

AAC intervention is recognized as appropriate treatment for individuals with severe apraxia who are unable through traditional speech-language treatment methods to restore natural speech and communication needs arising in their daily activities (Duffy, 1995). A speaker with severe apraxia may produce no speech or perhaps a few stereotypical utterances that may or may not be meaningful. Speakers also may exhibit extensive groping in an apparent attempt to achieve articulatory targets. Imitation of even very simple utterances (*e.g.*, 'me,' 'no,' 'bye') probably will be difficult. Individuals with severe apraxia also will exhibit considerable frustration. Some individuals will respond to their frustration by repeated phonation and groping movements accompanied by gesture. Others may give up and not want to initiate any attempts at speech. The diagnosis of apraxia is made by an SLP based on a speech/language evaluation. While there are published tests (Dabul. 1979; Di Simoni. 1989) that measure speech-motor function and assist in the diagnostic process, the most important assessment tools are the eyes and ears of the examiner an audio or audio-video recorder and a systematic series of tasks for observing non-speech (vegetative) and speech programming abilities (Duffy, 1995).

Typically, a recommendation for AAC intervention in apraxia occurs after an unsuccessful period of traditional speech therapies. The beneficial effects of traditional speech treatment are well documented for some individuals with apraxia (Cherney, 1995; Deal & Florance, 1978; Dworkin, Abkarian, & Johns, 1988; Dworkin & Abkarian, 1996; Howard & Valley, 1995; Rosenbek, Lemme, Ahern, Harris, & Wertz, 1973; Wambaugh, Kalinyak, Michelene, West, & Doyle, 1998a; Wambaugh, West, & Doyle, 1998b; Wertz, 1984). Unfortunately, with severe apraxia even extensive drill and practice may not bring about the return of functional, natural speech. For these individuals, AAC intervention is appropriate. The following questions are pertinent: (1) what is the prognosis for the return of natural speech; (2) if AAC intervention is appropriate, should it consist of a gestural system, writing, the use of a communication board (Skelly, Schinsky, Smith, & Fust, 1974; Rosenbek, 1985), and/or an electronic device. If an electronic device is appropriate, the AAC assessment is carried out as outlined in Subpart II of this section. AAC devices are available that offer individuals with apraxia features that enhance their communication effectiveness in their daily lives (small, portable devices that store vocabulary, options to use symbols/words, speech output with intelligible female/male voices and rate enhancement options). Preliminary studies demonstrate that AAC devices effectively can improve the functional communication of some individuals with severe dyspraxia/apraxia and are a necessary treatment option.

2. The Use And Efficacy Of AAC Devices For Treatment Of Apraxia

The professional literature related to treatment of apraxia of speech includes a number of reports describing AAC interventions using electronic devices. One early study reported on three individuals who used one of the first voice output communication devices. Although more appropriate technology is available today, these early reports document that AAC devices can have an important impact on the lives of individuals with severe apraxia. For example, one woman who prior to AAC intervention would not leave her home, considered herself 'communicatively independent' after she learned to use the AAC device and was able to return to nearly all of the same activities she engaged in premorbidly (Radioux, Forance, & McCauslin, 1980).

AAC devices are reported to enable individuals with apraxia to achieve a variety of functional goals. For example, Yorkston & Waugh (1989) give an account of an individual who had a combination of apraxia of speech, limb apraxia, and aphasia, which made it impossible to respond even to simple yes/no questions using natural speech or gestures. This failure to respond often is attributed to poor auditory comprehension skills but also may be due, at least in part, to the inability to formulate an adequate response. She learned to use an AAC device to indicate 'yes' and 'no' and appeared to benefit from the additional cueing provided by the visual presence of the symbol on a display and auditory signal of the speech synthesized word.

Another case example is that of a 47 year old interior designer who experienced a left CVA with severe apraxia and moderate aphasia. Yorkston & Waugh (1989) and Beukelman, Yorkston, and Dowden (1985) described a period of traditional speech therapy that included the development of a multi-component, non-electronic AAC system. Three years post stroke, when the client wished to return to his business, an electronic AAC device was programmed with conversational control phrases that allowed the client to initiate, direct, and terminate conversations with his clients. Reportedly, the AAC device enabled the client to return to work.

More recently, Murray (1997), Rogers & Alarcon (1997), Rogers & Alarcon (1998) reported on the use of an AAC device for individuals with apraxia and progressive aphasia. In the Roger's case, a five-year trajectory of the communication impairment and intervention was described. Speech symptoms began with apraxia of speech and later developed into a decline in appropriate use of grammar, decrease in writing skills, auditory comprehension decline, reading decline, and finally mutism. Treatment strategies paralleled the onset of symptoms beginning with pacing of the speaking rate and progressing to strategies involving the identification of topic and key words, gestural and drawing systems, a communication book, and finally a synthesized speech AAC device with access to symbol-based pre-selected messages. The individual was able to use the AAC system successfully despite severe impairment.

C. Characteristics Of Speech Language Impairment Requiring AAC Treatment: Aphasia

Aphasia is the impairment of the second link in the communication chain involving an individual's ability to understand and formulate language. It typically occurs as a result of brain damage involving the language-dominant cerebral hemisphere. Depending upon its severity, aphasia significantly can affect an individual's ability to converse, exchange information, and in some cases, to communicate basic needs. Language and communication can be permanently altered. Individuals who previously communicated with no difficulty suddenly find themselves unable or limited in their ability to participate in the vast range of communicative activities that typify human behavior (Holland, Fromm, DeRuyter, and Stein, 1996).

Severe aphasia profoundly impacts the daily life experiences of individuals because the automaticity and accuracy of their communication is affected. Individuals with aphasia usually have reduced abilities in all language and communication modalities, including speaking, auditory comprehension, reading, writing, and communicating through gestures or pantomime. The degree of impairment in each modality may differ, which creates distinct patterns of communication disability (Broca's/nonfluent aphasia, Wernicke's/fluent aphasia, transcortical sensory aphasia, anomic aphasia) (Benson & Ardilla, 1996; Davis, 1993; Goodglass & Kaplan, 1983).

From a medical perspective, aphasia generally is considered a relatively stable condition after the first few months post insult. For example, in persons who have recently sustained a stroke, most motor recovery takes place within 3-6 weeks, although upper extremity functioning may continue to improve over 6 months. With regard to language function, the first six months post insult is considered the period during which most spontaneous recovery will occur (Culton, 1969; Kertesz & McCabe, 1977). However, long-term improvement in communication skills may take place for months and even years (Benson & Ardilla, 1996; Kertesz, 1988; Poeck, Huber, & Willmes, 1989). The mechanisms for this type of long-term recovery are not well understood but explanations point to therapy (Darley, 1975), strategy learning (Penn, 1987), or functional systemic reorganization (Luria, 1963, 1976). One exception to this pattern of immediate recovery followed by long-term improvement is the relatively rare condition of primary progressive aphasia. These individuals demonstrate a gradual speech and language deterioration of unknown etiology (Mesulam, 1982; Tyler, Moss, Patterson, & Hodges, 1997).

Few individuals with aphasia regain sufficient verbal communication skills to participate fully in adult communication activities, *i.e.*, talking with family members, conducting transactions in the community, interacting in the workplace, or sharing life experiences with others. Such limitations have resulted in social isolation and deterioration in life satisfaction for many individuals with aphasia (Kinsella & Duffy, 1979; Parr, 1994). Persons with aphasia report that their activities are restricted, their interpersonal relationships are negatively impacted, and their autonomy is lessened (LeDorze & Brassard, 1995). Approximately 70 percent of those who responded to a National Aphasia Association survey felt that people avoided contact with them because of their difficulty with communication. Despite speech-language therapy, 72 percent of all individuals with aphasia could not return to work (National Aphasia Association, 1987). Individuals with severe and global aphasia often are so profoundly affected that they cannot always communicate adequately to meet their basic needs (Collins, 1986; Garrett & Beukelman, 1992).

Treatment for severe aphasia focuses on improving functional communication skills as well as remediating speech and language impairments. As a result, many individuals with severe aphasia rely on a range of low-tech AAC strategies including picture books, partner-assisted communication strategies, gestures, and word boards. Others benefit from the use of electronic, voice output AAC devices to express basic needs, exchange information, engage in social interaction, and participate more actively and independently in daily activities. Studies demonstrate that AAC devices are effective in treating some of the communication difficulties associated with severe aphasia.

By far the most common cause of aphasia is stroke, although aphasia also may result from brain tumors, head injuries, or other insults to areas of the brain that mediate language processing. Strokes in the language-dominant hemisphere (typically the left hemisphere) result in 80,000 new cases of aphasia annually (National Institute on Neurological Disorders and Stroke, 1990; Broderick, Brott, Kothari, Miller, Khoury, Pancioli, Gebel, Mills, Minneci, & Shukla, 1998). The prevalence of aphasia in the United States is estimated at approximately one million people. Most of these individuals are over the age of 60. The incidence of aphasia is equal for males and females, and persons of all races, educational, and social-economic backgrounds experience aphasia (National Aphasia Association, 1987).

Research shows that recovery following an insult or injury to the brain varies considerably across individuals as a result of biological and neurological factors (Basso, 1992). However, several factors have been found to be predictive of positive outcomes following stroke. Marshall and Phillips (1983) found that verbal communication outcomes in 80 aphasic men could be predicted 86 percent of the time by 6 variables: 1) initial severity of aphasia, 2) number of months after stroke, 3) auditory comprehension ability, 4) age, 5) speech fluency, and 6) general health. In general, younger patients recover better than older patients, individuals with large lesions or mass effects do more poorly than those with focal infarcts, patients with poor auditory comprehension regain fewer language skills than those with good comprehension, and those patients who receive treatment earlier regain more function.

With regard to recovery of speech and communication skills, some individuals with aphasia experience a nearly complete recovery of their language capabilities. Others demonstrate mild or moderate language impairments that reduce the efficiency of their communication. There also is a significant number of persons with aphasia for whom severe communication disorders are permanent. Global aphasia, or aphasia with profound impairment across all language modalities, is in fact, the most common type of aphasia. Alexander and Loverso (1991) reported that of 850 cases of stroke admitted to an urban hospital, 21 percent were aphasic, and 41 percent of these patients were diagnosed with global aphasia. At four to twelve weeks post onset, 33 percent of the patients with global aphasia were dead, 22 percent had progressed to milder forms of aphasia, and 44 percent continued to receive the classification of global aphasia. Persons with severe or global aphasia often benefit from the use of a range of AAC treatments.

1. AAC Devices As Treatment For Aphasia

Historically, treatment for aphasia reflected an impairment model with treatment focusing on improving speaking, comprehending, reading, and writing, typically by means of various 'stimulation' approaches in which the individual practiced communication sub- skills in the targeted modality. This type of traditional speech and language rehabilitation, typically administered by SLPs has been evaluated extensively in large- and small-group investigations, well-controlled single-subject experimental studies, and single case efficacy studies. Positive outcomes of speech and language therapy are documented extensively for individuals across settings and treatment conditions (Aten, Caligiuri, & Holland, 1982; Basso, Capitani, & Vignolo, 1979; Elman, 1999; Homan, 1991; Poeck, Huber and Willmes, 1989; Robey, 1994; Robey, 1998; Wertz, Collins, Weiss, Kurtzke, Friden, Brookshere, Pierce, Holzapple, Hubbard, Porch, West, Davis, Matorich, Morley & Resurrecion, 1981; Wertz, Weiss, Aten, Brookshire, Garcia-Bunuel, Kurtzke, La Pointe, Milianti, Brannegan, Greenbaum, Marshall, Vogel, Cortes, Barnes and Goodman, 1986).

More recently, treatment for aphasia has broadened from a focus at the level of impairment to the level of disability. (Elman, 1999; Homan, 1991; Hopper and Holland, 1998; Kagan, 1998; Lasker, Hux, Garrett, Moncrief and Eischeid, 1997). Thus, the emphasis of treatment even in the early stages of spontaneous recovery, addresses an individual's need to communicate immediately in the face of severe speech and language impairment. Nicholas and Helm-Estabrooks (1990) noted that the restoration of speech is not realistic for many individuals with severe aphasia. They advocated shifting the goals of treatment from talking to communicating through alternative modalities. Likewise, Wallace and Canter (1985) suggested that language treatment with severely aphasic adults should maximize the individual's communication in the day-to-day environment. In conjunction with this shift, AAC approaches increasingly have been incorporated into comprehensive management approaches for persons with severe aphasia (Fox & Fried-Oken, 1996; Garrett & Beukelman, 1998; Kraat, 1990).

SLPs use a number of well-known tests, standardized for the evaluation of aphasia. Examples are the *Western Aphasia Battery* (Kertesz, 1982); *the Boston Diagnostic Aphasia Examination* (Goodglass & Kaplan, 1983); *the Boston Assessment of Severe Aphasia* (Helm-Estabrooks, Ramsberger, Morgan, & Nicholas, 1992); *Revised Token Test* (McNeil & Prescott, 1978); and the *Porch Index of Communicative Ability* (Porch, 1981). These instruments help to determine the existence and severity of aphasia and differentiate between the various types of speech and language impairments that occur with aphasia. They also enable clinicians to develop a profile of linguistic strengths and weaknesses. More recently developed test instruments, such as the *ASHA Functional Assessment of Communication Skills (ASHA-FACS)* (Frattalli, Thompson, Holland, Wohl, & Ferketic, 1995) and the *Communicative Abilities in Daily Living (CADL)* (Holland, Frattali, & Fromm, 1999), document how aphasia affects the individual's ability to use speech and language functionally in real-life contexts.

To better determine which individuals with aphasia will benefit from AAC treatment approaches and what type of treatment approaches are most efficacious, Garrett and Beukelman (1992) developed the following *Classification System for Individuals with Severe Aphasia*. This paradigm increasingly guides assessment and treatment planning among SLPs working with individuals with severe aphasia. The paradigm summarized in

TABLE 3 describes types of severe aphasia and suggests specific treatment approaches that can enhance functional communication and improve the short- and long-term outcomes for these individuals.

TABLE 3: CLASSIFICATION SYSTEM FOR INDIVIDUALS WITH SEVERE APHASIA[7]

TYPE OF SEVERE APHASIA	DESCRIPTION	TREATMENT GOALS
Basic-Choice Communicator. (Chronic global aphasia with severe neurological impairment).	Profound cognitive-linguistic disorder across modalities. With maximal assistance, can make basic choices and develop turn-taking skills in familiar contexts. <u>Note</u>: Shortly after a stroke, many individuals with aphasia function as basic-choice communicators. Those with persistent global aphasia remain basic-choice communicators for an extended period of time.	Provide simple system for communicating basic messages and prepare for more advanced types of communication strategies when, and if, the individual improves medically. Need for speech output AAC devices is minimal.

7 Adapted from Garrett & Beukelman (1992).

Controlled-Situation Communicator. (Chronic global aphasia, Broca's aphasia, Wernicke's aphasia).	Often are isolated socially. Can initiate communication with assistance in structured situations. Can indicate needs by spontaneously pointing to objects and items. Many have a limb apraxia, and speech is often stereotypic or nonexistent. Individuals are aware of daily routines and can participate in conversations and communicate specific information, opinions, and feelings when supported.	Provide AAC treatment to enable person to express basic needs, talk on phone, provide basic social information and communicate medical/ emergency information. Some benefit from digitized speech AAC devices. Teach caregivers to use 'written-choice communication.
Comprehensive Communicator. (Chronic Broca's aphasia and conduction aphasia).	Retain a variety of communication skills (drawing, gestures, limited speaking abilities, first-letter of word spelling and pointing to words or symbols). Communication efforts are often fragmented or inconsistent, *i.e.*, they often can provide scraps of information.	Use low-tech communication notebook or wallet to supplement impaired speech. Some use digitized AAC devices for transactions in the community and to engage in specific conversations where intelligible speech is mandatory (talking to doctor, on the phone). Some demonstrate cognitive-linguistic ability, partner support, and extensive vocabulary needs to use synthesized AAC devices.
Augmented-input Communicator. (Wernicke's aphasia).	Have auditory processing difficulties that interfere with the comprehension of spoken language. During conversations, may nod their heads, but this often signals 'listening' rather than a comprehension of the language being spoken.	Minimize conversational breakdowns by teaching communication partners to write, show photographs, draw, or use symbols and diagrams to represent key words and topics as they speak. Some use digitized AAC devices.
Specific-need Communicator.	Most of the time, manage communication through gestures and their limited speech. Require support in situations that call for specificity, clarity, or efficiency.	Enable individuals to carry out specific communication tasks using AAC treatment approaches. May require a digitized speech output AAC device over the telephone or for transactions in the community.

The selection of an appropriate AAC device for an individual with aphasia follows the same data gathering process described in Subpart II of this Section. The assessment process gathers data that relates to the individual's linguistic skills, functional communication skills, nonverbal communication skills, motor skills, sensory skills, perceptual skills, pragmatic skills, experiential skills, and daily communication needs.

2. The Use And Efficacy Of AAC Devices As Treatment For Aphasia

AAC strategies and devices have been shown to be effective for persons with aphasia (Fox & Fried-Oken, 1996; Garrett & Beukelman, 1998; Kraat, 1990; Steele, Weinrich, Wertz, Kleczewska, & Carlson, 1989). Many individuals with severe aphasia are candidates for communication notebooks or wallets, alphabet boards for first-letter spelling, and 'yes-no' boards (Beukelman, Yorkston, & Dowden, 1985; Fox, Sohlberg, & Fried-Oken, in press; Yanak & Light, 1991). In addition, AAC devices can enable people with aphasia to become more independent in the community, communicate functional needs more specifically, participate more fully in social exchanges, tell stories, and make telephone calls (Garrett and Beukelman, 1998; Hopper & Holland, 1998).

According to Fox and Fried-Oken (1996), outcome studies in AAC and aphasia fall into four broad classifications: comprehensive case studies, carefully controlled single-case experimental studies, group studies and other types of descriptive or comparative studies. For example, Belliare, Georges and Thompson (1991) used a multiple-baseline design to demonstrate that when individuals with severe aphasia are taught to use communication boards designed to meet their needs in a natural setting, learning occurs and generalization takes place.

In 1985, Beukelman, Yorkston, & Dowden described an aphasic adult who used a variety of communication methods at home and at work. The subject had severe verbal apraxia and a moderate-severe aphasia and used the Handivoice 130 (an AAC device with synthesized speech that is no longer available) to communicate a restricted number of messages. The device enabled the subject to return to work. The authors concluded that the use of an AAC device was an important part of the subject's more comprehensive communication system, which included (1) a communication notebook (words related to specific needs), (2) a more general conversational photograph album, and (3) gestures, facial expressions, and intonation.

Garrett, Beukelman, and Low (1989) described a case in which an individual with Broca's aphasia (*i.e.*, limited expressive language skills and good receptive skills) learned to use a multi-component AAC system in various community environments. The AAC device contained individualized messages that the client used successfully to obtain veteran's benefits and community-based transportation. In addition, during a controlled clinical interaction, the authors documented that when the individual used his AAC system, he experienced a decrease in communication breakdowns (from 50 percent to 17 percent of all communication turns) and an increase in the number of successful communication turns as compared to when he relied solely on speech and gestures.

In 1989, Steele and his colleagues showed that a subject with global aphasia was successful in communicating trained syntactical forms using an AAC device (Weinrich, et. al., 1989). Using an alternative treatment design, Steele, Kleczewska, Carson & Weinrich, 1992 compared a single aphasic person's ability to comprehend instructions given three different language modalities: (1) a computer-based system that used icons; (2) written commands, and (3) spoken commands. The subject consistently performed better when the commands were given using the AAC device. They concluded that the device was a superior input communication modality for this type of task with this type of patient.

Beck and Fritz (1998) studied a group of 10 people with aphasia, 5 with anterior aphasias and 5 with posterior aphasias, and a group of 10 non-brain-damaged controls to investigate four questions: (1) Can people with aphasia learn iconic encoding? (2) Does the ability to learn iconic encoding vary with different types of aphasia? (3) Does the level of abstraction of the messages affect the ability to learn iconic encoding? (4) Does the length of an icon sequence affect the ability to learn iconic encoding? Results indicated that people with aphasia can learn iconic encoding under specific conditions. The type of aphasia, level of abstraction, and length of icon sequence influenced learning.

Waller, Dennis, Brodie, Cairns, (1998) describe the design and evaluation of a computer-based communication system called 'TalksBac' with four nonfluent adults with aphasia. The system is word-based and exploits the ability of some nonfluent aphasics to recognize familiar words and short sentences. At the end of a 9-month training period, each subject's communication skills were reassessed by use of a battery of tests comparing skills with and without the TalksBac system. The results indicated that two of the subjects improved in their conversational abilities using the system. The researchers concluded that TalksBac has the potential to augment the communication abilities of some nonfluent adults with aphasia. Work continues to improve the efficiency of the software.

Fox, Sohlberg, & Fried-Oken (1999) investigated the outcomes of AAC intervention for adults with severe nonfluent aphasia. Subjects had severely limited spoken language abilities with moderate-to-mild auditory comprehension impairment. Results showed that aphasic subjects used their conversational communication aids increasingly well over time in a clinical environment. In addition, researchers reported that the subjects also used their devices in natural environments. Finally, Kagan (1995) reported that individuals with aphasia can communicate effectively with medical professionals who have been trained to use AAC strategies in ways that support conversations with their patients. Other studies also have documented the importance of appropriate partner training and support for successful AAC use (Garrett & Beukelman, 1995; Lasker, Hux, Garrett, Moncrief, & Eischeid, 1997).

II. CLINICAL DECISION MAKING PROCESS

A. AAC Assessment Process

Clinical decisions regarding AAC intervention are made in the context of a comprehensive speech-language assessment. The AAC assessment process is well established in the professional literature as well as in standards of practice for SLPs (ASHA Standards of Practice, Clinical Competencies in AAC, Yorkston (in press); Beukelman and Mirenda (1998). The assessment process begins with data gathering, as described below and in the Flow Chart depicted in Figure 1 that follows this section on page 45. It requires a series of clinical decisions that determine the diagnosis and severity of the disabling condition (dysarthria, apraxia, and/or aphasia) and the kind of speech-language pathology treatment that is required to achieve functional communication goals, including AAC treatment where indicated.

The outcome of an AAC assessment is a narrative report, which describes the clinical facts relevant to a beneficiary's speech-language impairment, the need for AAC treatment, and when recommended, information germane to the selection of an AAC device. The assessment report also includes an AAC treatment plan that states the functional communication goals the beneficiary is expected to achieve with the AAC device. The AAC treatment plan is based on the clinical facts presented and the application of the SLP's professional judgment regarding the specific AAC treatment.

1. Clinical Decisions Leading To The Selection Of An AAC Device

In the course of the AAC assessment process, the SLP makes six major clinical decisions regarding the need for AAC treatment and the type of AAC treatment required. These decisions are highlighted in red along the left margin of the Flow Chart (FIGURE 1). The six AAC assessment decisions include: (1) determining current functional communication levels; (2) predicting future levels of communication effectiveness; (3) identifying functional communication goals and treatment approaches; (4) selecting specific AAC treatment approaches; (5) selecting an AAC device and accessories; and (6) procuring, training, and following up.

a. DECISION #1: Determining Current Functional Communication Levels

Assess current communication needs. (Box (a), FIGURE 1). The SLP first determines the type, severity, and anticipated course of the individual's communication impairment. This portion of the assessment process confirms the diagnosis of severe dysarthria, apraxia, or aphasia. In addition, the SLP seeks to identify the individual's daily communication needs in order to establish functional communication goals for treatment. The scope of an individual's communication needs may range from simple expressions of wants and needs to a caregiver, to the communication of complex thoughts and ideas to family, friends, and services providers across multiple settings. The product of the assessment will be an individualized profile of communication needs with an indication of the importance for each need category (Yorkston, 1999; Beukelman and Mirenda, 1998; Blackstone, 1985).

Assess communication effectiveness. (Box (b), FIGURE 1). Using the individualized communication needs profile, the SLP considers whether, given the severity of the individual's current level of speech and language impairment, the daily communication needs can be met using natural modes of communication. The assessment determines whether an individual is able to communicate effectively using natural speech in typical conversations and other communication occurrences that arise throughout the individual's daily activities.

b. DECISION # 2: Predicting Future Levels of Communication Effectiveness

Assess potential for deterioration in natural communication skills. (Box (c), FIGURE 1). The SLP determines the likelihood that there will be deterioration in communication effectiveness due to the natural course of the individual's condition. For example, after noting that an ALS individual's speech intelligibility has worsened, the SLP may predict that communication through natural modes will become impossible and recommend AAC treatment in anticipation of this deterioration.

When communication needs are met, no treatment is recommended. (**Box (d), FIGURE 1**). When the assessment process shows that individuals are able to meet their communication needs through natural communication methods, and their condition is not expected to deteriorate further, then no treatment is recommended.

c. DECISION # 3: Identifying Functional Communication Goals and Treatment Approaches

Identify functional communication goals. (**Box (e), FIGURE 1**). When recommending AAC treatment, the SLP defines a list of functional communication goals. According to Medicare guidance, functional communication goals 'reflect the final level the patient is expected to achieve, are realistic, and have a positive effect on the quality of the patient's everyday functions.' Functional goals may be a 'small, but meaningful change that enables the beneficiary to function more independently in a reasonable amount of time.' Medicare Intermediary Manual (HCFA Pub. 13) ('MIM') § 3905.3(A); Medicare Hospital Manual (HCFA Pub. 10) ('MHM') §446(a)(3)(A). Functional communication goals may range from an ability to: indicate yes/no responses; communicate basic physical needs or emotional status; communicate self-care and medical needs; use a basic spoken vocabulary and short phrases; engage in social communication with family and friends; engage in communicative interactions in the community; utilize conversational language skills; talk on the telephone; or respond to emergencies. MIM §3905.3(A); MHM, §446(a)(3)(A).

Assess potential to improve natural communication methods. (**Box F, FIGURE 1**). The purpose of this assessment is to determine whether functional communication goals can be achieved using speech, writing, or gestures. Where natural communication methods have the potential to meet communication needs, an SLP will recommend treatment to improve natural speech or language performance. (**Box G, FIGURE 1**). For some individuals, sustained treatment to improve their natural speech and language capability is sufficient to return them to communication effectiveness, and AAC treatment is not recommended. However, when individuals with severe dysarthria, apraxia, and/or aphasia do not demonstrate the potential to meet their communication needs using natural methods, the SLP will recommend AAC treatment approaches to improve communication effectiveness and achieve functional communication goals. (**Box H, FIGURE 1**).

At this point of the clinical decision making process, the SLP has determined that an individual will require treatment involving AAC treatment techniques. This judgment is based on the individual's diagnosis of severe dysarthria, apraxia, and/or aphasia and his/her inability to meet current or future communication needs using natural communication methods. The next portion of the clinical decision making process leads the SLP, often in collaboration with other allied-health professionals, determines the type of AAC treatment required, the type of AAC device and device accessories needed, and the specific treatment plan that will be implemented.

d. DECISION # 4: Selecting Specific AAC Treatment Approaches

Select AAC treatment options. (**Box (I), FIGURE 1**) AAC treatments may include three different approaches to augmenting spoken communication: (1) speech output AAC devices (also known as 'high technology' devices); (2) non-electronic aids such as alphabet, word, and picture boards; and (3) unaided communication strategies such as gestures, listener-supported AAC techniques, and sign language. Most individuals use a combination of these approaches.

TABLE 4 below lists nine clinical indicators for speech output AAC device selection. Their use in the AAC assessment process lead to the selection of an AAC device from among the three categories delineated in Section 5. In addition, these clinical indicators are used as coverage criteria for AAC devices as proposed in Section 6.

TABLE 4: CLINICAL INDICATORS REQUIRED FOR AAC DEVICE SELECTION

1	The individual has a communication disability with a diagnosis of severe dysarthria, apraxia, and/or aphasia.	Y	Y	Y
2	The individual's communication needs that arise in the course of current and projected daily activities cannot be met using natural communication methods.	Y	Y	Y
3	The individual requires a speech output communication device to meet his/her functional communication goals.	Y	Y	Y
4	The individual possesses the linguistic capability to formulate language (messages) independently.	N	Y	Y
5	The individual will produce messages most effectively and efficiently using spelling.	N	Y	Y or N
6	The individual will require an AAC device with extensive language storage capacity and rate enhancement features.	N	N	Y
7	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..	Y or N	Y	Y or N
8	The individual will access the AAC device most effectively and efficiently by means of an electronic accessory that permits direct selection.	Y or N	N	Y or N
9	The individual will access the AAC device most effectively and efficiently by means of an indirect selection technique (*e.g.*, scanning, Morse Code).	Y or N	N	Y or N

The first two clinical indicators lead to consideration of AAC treatment approaches as described above: *The individual has a communication disability with a diagnosis of severe dysarthria, apraxia, and/or aphasia* to which a positive response is required. And, *the* *individual's communication needs that arise in the course of current and projected daily activities cannot be met using natural communication methods.* To which a positive response is required. The third clinical indicator *the individual requires a speech output communication device to meet his/her functional communication goals* requires a positive response. Some functional communication goals only can be met if a person has access to a speech output communication device.

e. DECISION # 5: Selecting an AAC Device and Accessories

After considering the remaining clinical indicator, the SLP will select from among the three categories of AAC devices described in Section 5.

Determine message formulation capability: (**Box (J), FIGURE 1**). *The individual possesses the linguistic capacity to formulate language (messages) independently.* Some individuals who are unable to meet their communication needs through natural speech are able to spell and/or sequence words or symbols in ways that allow them to generate sentences and narratives independently. If the response to the fourth clinical indicator is no, then the individual will require a 'whole message' AAC device. (**Box (K), FIGURE 1**). Individuals who experience cognitive or language impairments and are unable to formulate their messages by spelling or word-by-word development may include persons with aphasia due to cortical stroke as well as those with congenital (mental retardation) and acquired conditions (Huntington's disease, progressive aphasia, and some individuals with severe traumatic brain injury). These individuals typically use AAC devices from the first category (digitized speech output). These systems provide the user with an entire phrase, sentence, or narrative with a single selection on their communication device.

Alternately, if the response to the fourth clinical indicator is yes, then the individual will require a device from the synthesized AAC device categories. (**Box (L), FIGURE 1**). Typically, these individuals have dysarthria secondary to primary physical impairments caused by ALS, cerebral palsy, brain stem stroke, multiple sclerosis, and Parkinson disease, and those persons with traumatic brain injury who have relatively preserved linguistic and cognitive skills. These individuals can generate messages independently using words, letters, or graphic symbols.

Determine need to generate messages by use of spelling: (**Box (M), FIGURE 1**). *The individual will produce messages most efficiently and effectively using spelling.* The AAC assessment process determines whether a person can spell sufficiently well to generate messages. If the answer is yes, then the individual will require a synthesized speech device because they can generate spoken messages using spelling. The assessment determines whether the individual has sufficient spelling abilities to generate messages independently.

Determine if person generates language most efficiently and effectively with a system that has extensive storage and rate enhancement features: (**Box (N), FIGURE 1**). *The individual will require an AAC device that provides extensive language storage capacity.* The AAC assessment process determines whether an individual who can generate language independently has the need to store and retrieve a large amount of language to meet their functional communication goals. For example, individuals wishing to prepare messages in advance, as well as those who need to provide large amounts of information such as to describe changes in the individual's medical condition or reactions to medication to a doctor at a periodic appointment, or to be able to quickly ask questions related to a shopping list, require AAC devices with the capacity to store previously created messages and enable them to retrieve their stored messages efficiently and effectively. These features are described in Section 5. The assessment determines whether an individual has the need to use an AAC device with extensive language storage and retrieval capacity. AAC devices in category 3 offer these options.

Determine ability to use direct selection access. **(Box (O), Figure 1).** There are a range of access methods for AAC devices. Two involve direct selection: (1) direct physical contact using a finger, another body part, stylus, hand-held pointer, head stick, or mouth stick, or (2) direct selection techniques using an electronic accessory. A third access method utilizes indirect selection using switch-based scanning.

The AAC assessment process for the seventh clinical indicator *the individual will access the AAC device most effectively by physical contact direct selection technique, such as with a finger, other body part, stylus, hand held pointer, head stick or mouth stick* and the eighth clinical indicator: *the individual will access the AAC device most effectively by means of an electronic accessory that permits direct selection* often *may* require the knowledge and skills of other allied-health professionals to determine the most effective method of access. When a direct selection accessory is needed, the AAC assessment determines the type required. Section 5 discusses these options. If the individual is able to spell and does not have extensive needs for language storage and can use direct physical access, the SLP will recommend a device from Category #2. Devices in Categories #1 and #3 offer multiple options for direct access.

Determine ability to use indirect access (switches). **(Box (P), Figure 1).** When individuals have severe physical impairment that preclude access to AAC devices using direct selection, the SLP will consider alternative selection options. The ninth clinical indicator asks: *the individual will access the AAC device most effectively and efficiently by means of an indirect selection technique (e.g., scanning, Morse Code).* This portion of the AAC assessment is often conducted in collaboration with other allied-health professionals because of the motor impairments that preclude direct access to the AAC device. Section 5 provides information on scanning-based selection techniques, Morse code, and use of switches. The product of this assessment is the determination that an individual can use an indirect selection technique. All device categories except for Category #2 offer this option.

For Medicare reimbursement purposes, where the SLP has considered all the clinical indicators and made decisions about the category of AAC devices that is appropriate for the individual and the need for device accessories, if any **(Box (Q), Figure 1)** the process ends here, but for the SLP, the process continues. The SLP must recommend a specific device and address training needs. These determinations are based on all the facts gathered during the assessment but rely most directly on the nine key clinical indicators.

Specific AAC device recommendation. After determining that a voice output AAC device will be appropriate for the individual and identifying the appropriate category of AAC devices, the SLP matches the capabilities of the individual to the characteristics of a specific AAC device and device accessories. Typically, the matching process yields a short list of AAC device and accessory options from which the individual, family, and allied health professionals can select to enable the individual to achieve his or her functional communication goals and optimum level of communication independence.

Because of the complexity of human communication and the variation among people who benefit from using AAC devices, there is not a one-to-one relationship between the specific AAC device within any one category of devices and a group of end users. Within each category, specific AAC device choices will be made based on clinical factors as well as some individual preference factors. For example:

- Individuals who can use independent message formulation systems will require devices with synthesized speech output. Some, who are ambulatory and who want a small lightweight AAC device that will allow them to access vocabulary independently at multiple levels will select a Dynamyte, by Dynavox systems. This device is small, lightweight, and offers a dynamic display.

- Other individuals may wish to learn the coding approach known as Minspeak that offers unique rate enhancement and storage/retrieval features. They will select an AAC device manufactured by the Prentke Romich Company that is packaged with Word Strategy, Unity, or other software that use a Minspeak approach.

- Others may prefer to rely primarily on spelling and want a display that their communication partners can see as they generate messages. They may select the LightWriter from Zygo Industries, which can be accessed with either direct or scanning selection approaches.

- Individuals who can select whole messages independently typically require devices with digitized speech output. Decisions about which digitized speech device to use will depend upon the size of the vocabulary the user needs to access, the user's ability to retrieve messages that are stored, and how the user will access the device. For example, the Message Mate series by Words +, Inc. offer a variety of portable, durable digitized speech devices with varying amounts of memory (minutes of speech).

Finally, the SLP determines the extent to which specific no-tech strategies and low-tech aids will be used to complement the voice output AAC device and help the individual achieve his or her functional communication goals and 'optimum communication independence.' *See* MIM § 3905.3(A); *see also* MHM § 446(a)(3)(A).

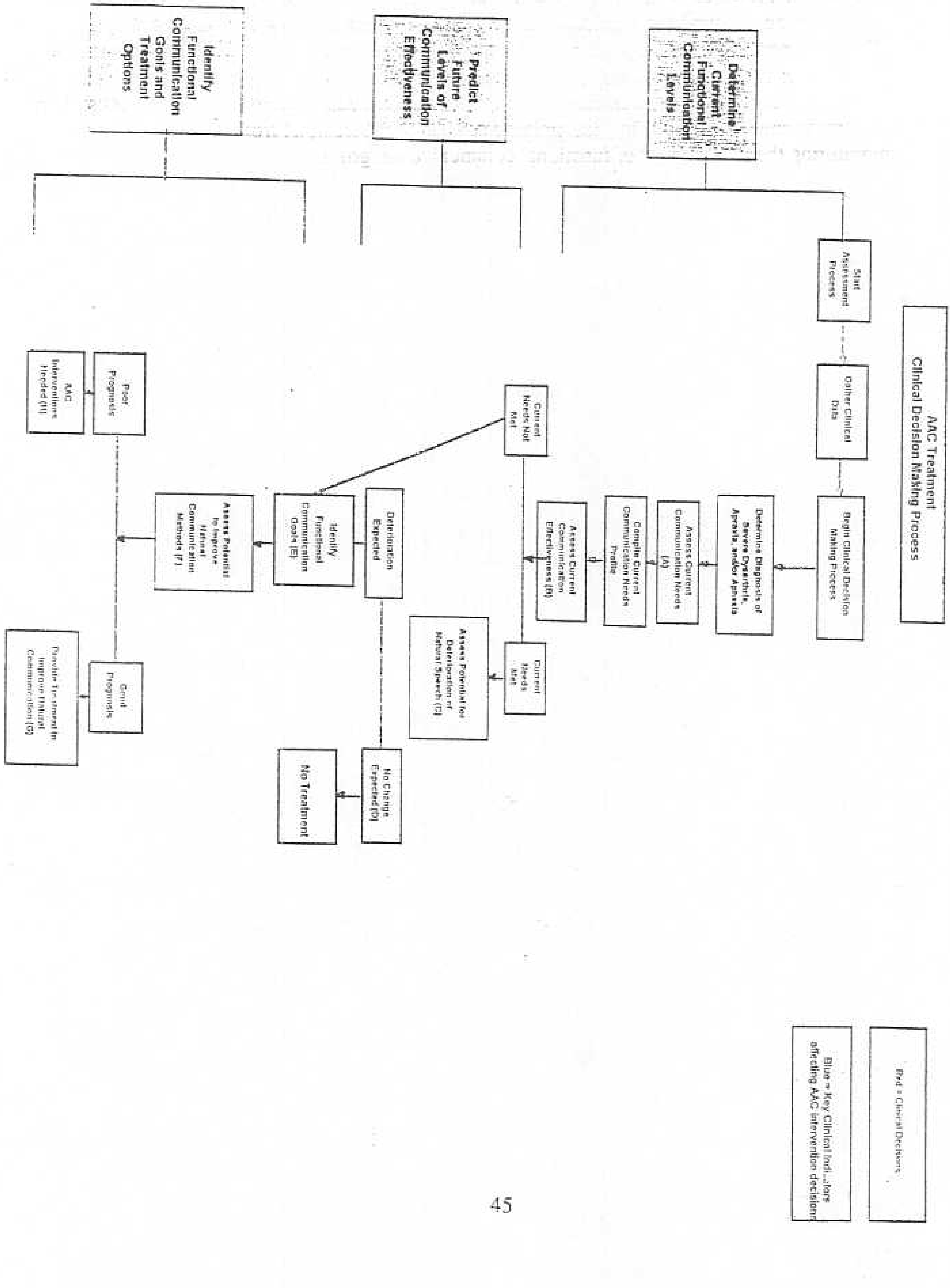
f. DECISION # 6: Determining Procurement, Training, and Follow Up

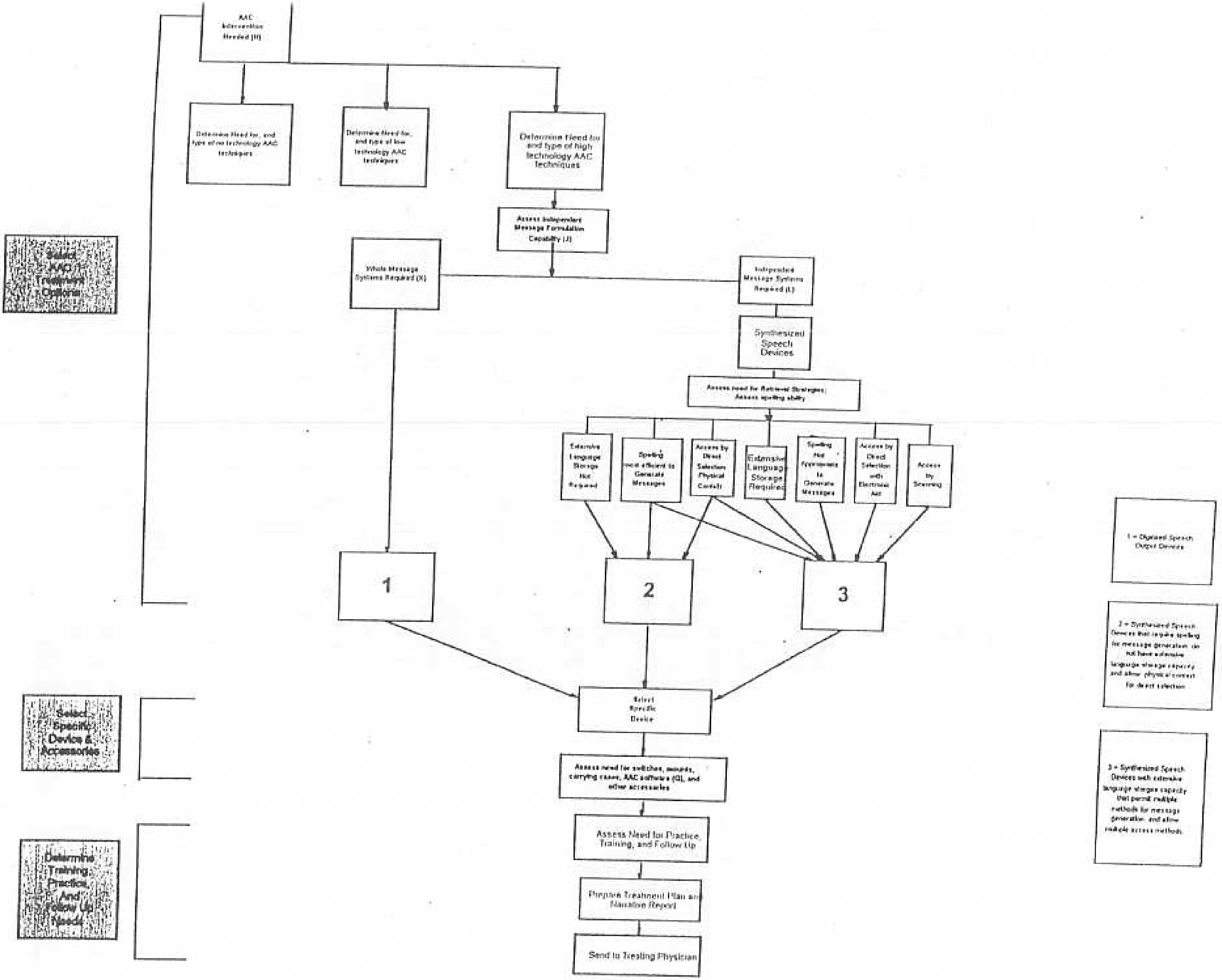
Because AAC devices will be new to individuals with severe communication disorders, a period of instruction and practice is required if the individual is to become communicatively effective in using an AAC device. SLPs often encourage a trial use prior to recommending the purchase of an AAC device. A trial use period may be appropriate when decisions are being made between similar devices, when it is unclear whether the environment will support the use of an AAC device, or when the individual or family is uncertain about whether to use an AAC device.

After a device is purchased and delivered, and an initial instruction and practice period has been completed, the SLP will complete a new communication needs assessment to determine whether the individual's current communication system, which now includes an AAC device, as well as residual natural communication and typically no-tech and low-tech AAC strategies, allows the person to communicate more effectively and achieve the functional communication goals. Over time, modifications of the configuration of the AAC device may be required to accomplish functional communication goals. Some individuals require follow-up to assist them with resolving technical difficulties, training new support personnel from time to time, and monitoring the achievement of functional communication goals.

FIGURE 1: AAC TREATMENT CLINICAL DECISION MAKING PROCESS FLOW CHART

(CONTINUED ON NEXT PAGE)




AAC Intervention Needed (H)
Determine Need for, and type of no technology AAC techniques
Determine Need for, and type of low technology AAC techniques
Determine Need for and type of high technology AAC techniques
Assess Independent Message Formulation Capability (J)
Whole Message Systems Required (K)
Independent Message Systems Required (L)
Synthesized Speech Devices
Assess need for Retrieval Strategies; Assess spelling ability
Extensive Language Storage Not Required
Spelling most efficient to Generate Messages
Access by Direct Selection Physical Contact
Extensive Language Storage Required
Spelling Not Appropriate to Generate Messages
Access by Direct Selection with Electronic Aid
Access by Scanning
1
2
3
Select Specific Device
Assess need for switches, mounts, carrying cases, AAC software (Q), and other accessories
Assess Need for Practice, Training, and Follow Up
Prepare Treatment Plan and Narrative Report
Send to Treating Physician
Select AAC Treatment Options
Select Specific Device & Accessories
Determine Training, Practice, And Follow Up Needs
1 = Digitized Speech Output Devices
2 = Synthesized Speech Devices that require spelling for message generation, do not have extensive language storage capacity and allow physical contact for direct selection
3 = Synthesized Speech Devices with extensive language storage capacity that permit multiple methods for message generation, and allow multiple access methods.

SECTION 4: MEDICARE COVERAGE OF AAC DEVICES AS ITEMS OF DURABLE MEDICAL EQUIPMENT IS APPROPRIATE

OVERVIEW

AAC devices meet the Medicare statutory standard as 'reasonable and necessary' to treat individuals with severe communication impairments. Like Medicare, the Medicaid programs focus on 'medical necessity' to determine coverage and payment of items and services. At present, AAC devices are covered by every state Medicaid program.[8] In addition, the Veterans Administration (now the Department of Veterans Affairs), CHAMPUS (now TriCare), and hundreds of commercial health insurance providers adopted coverage policies for AAC devices. (*See Myers v. State of Mississippi*, 1995).

AAC devices also meet the Medicare regulatory requirements for classification as items of durable medical equipment (DME) and are already so classified by numerous Medicaid programs which employ DME definitions identical to Medicare's definition. First, AAC devices are durable. Second, AAC intervention serves a medical purpose. Third, AAC devices are not useful absent an illness or injury, and AAC devices are designed, marketed, and sold exclusively to individuals with severe communication disabilities. Fourth, and finally, AAC devices are intended for home use, permitting an individual with severe communication disability to meet daily communication needs at home and wherever else those needs arise. In short, no one uses an AAC device in the absence of severe communication disability. Even the Food and Drug Administration (FDA) classifies AAC devices, which it describes as 'powered communication systems,' as 'medical devices' within the category Physical Medicine Prosthetic Devices. 44 *Fed. Reg*. 50,458, 50,489-90, (August 1979).

By contrast, Medicare currently does not cover AAC devices. Some time during the late 1980s, HCFA issued a National Coverage Decision (NCD), which appears as part of the 'DME Reference List.' The NCD states that coverage for Augmentative Communication Devices is denied because such devices are convenience items that are not primarily medical in nature as defined in section 1861(n) of the Social Security Act. Coverage Issues Manual, (HCFA Pub. 6)('CIM') § 60-9. Given the wealth of technical information provided in this Formal Request, the numerous professionals available for clarification, as well as past assurances by HCFA staff that further review would be unnecessary, we submit that HCFA can adopt the proposed NCD

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8 In addition, beginning in 1980 in New York State, AAC Device coverage criteria were developed to standardize decision making, a practice now followed by more than half the states. Yet another development during this period was the acknowledgement by Medicaid programs that the medical need for AAC devices was to treat the limitations arising from severe communication impairments, and was not based on the content of the speech produced by the AAC device, *i.e.*, the individual's ability to use the device to communicate with care-givers about other medical needs.

without referring it to the Medicare Coverage Advisory Committee (MCAC) or undertaking a technology assessment to review the findings presented.

Subpart I of this section describes how AAC devices meet Medicare's 'reasonable and necessary' coverage standard and meet the Medicare regulatory requirements for classification as DME and proposes Medicare coverage and payment categories for AAC devices. Subpart II describes the current coverage status of AAC devices including the history of the Medicare national coverage decision and explains why the current policy of non-coverage is erroneous and wholly inappropriate.

I. MEDICARE COVERAGE AND PAYMENT CATEGORY FOR AAC DEVICES

A. AAC Devices Meet The Medicare Statutory Standard As Reasonable And Necessary

The Medicare Act only pays for items or services that are 'reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member.' 42 U.S.C. § 1395y(a)(1). There are no Medicare Act regulations further defining the terms 'reasonable' and 'necessary.' In the 1987 *Federal Register* notice regarding NCDs, HCFA stated that a request for a NCD must show that the item or service is reasonable and necessary, which would require proof that the item or service is: a) safe and effective, b) not experimental or investigational, c) cost effective, and d) appropriate. 52 *Fed. Reg.* 15,560 (April 27, 1987). Although HCFA never published final regulations, these factors continue to be appropriate benchmarks. On December 6, 1999, Dr. Jeffrey Kang, M.D., Director of the HCFA Office of Clinical Standards and Quality, while speaking at the Medical Device Manufacturer's Association Second Annual Coverage and Reimbursement Conference in Philadelphia, referred to these four factors as general coverage factors, stating that the first two (safe and effective/not experimental or investigational) and last two (cost effective and appropriate) could be viewed as 'related' categories of information.

The Medicare program has not previously considered whether AAC devices are 'reasonable and necessary.' The existing Medicare AAC device guidance was not based on a review of medical literature or application of the 'reasonable and necessary' standard. AAC devices satisfy all the specific criteria HCFA has set for coverage. They provide treatment for specific, severe communication disabilities, and provide significant functional improvements in individuals' communication abilities. With AAC devices, individuals with severe dysarthria, apraxia and aphasia are able to meet the communication needs arising in their daily activities, and thereby are better able to participate more fully in their families and communities -- normal activities of daily living -- and to protect and improve their general health status. In addition, for those individuals who can achieve these functional outcomes through AAC device use, there is no alternate means of treatment that offers comparable benefits.

1. AAC Devices are Safe and Effective

In his December 6, 1999 presentation, Dr. Kang further clarified how HCFA determines an item or service is 'safe and effective.' He stated the term 'effective' means the item or service improves the health outcome of the patient as compared with the natural history of the disease.

He also stated that HCFA would find an item or service to be effective based on proof that 'the item or service improves a health outcome or provides an intermediate outcome with known links to a desired outcome and there is no medically effective alternative to compare the item or service with.' Dr. Kang then distinguished this description of 'effective' from the FDA standard of 'efficacy,' which he described as meaning that the item or service does what it is diagnostically or therapeutically designed to do. Medicare's requirement for effectiveness, in contrast, he explained, requires proof that the treatment provides health benefits, not merely that it works. Thus, FDA classification of AAC devices merely is the starting point for the HCFA coverage process.

AAC devices, as a class of medical devices, are safe, effective, and efficacious. 48 Fed. Reg. 53,032, 53,049 (1983). For the past 16 years, AAC devices have been classified by the FDA as 'powered communication systems' and thus meet its standards for safety and effectiveness, or 'efficacy.' 21 C.F.R. § 890.3710. AAC devices, as a class of medical devices, also meet the additional proof required by Medicare to be effective. First, as explained in Section 3, the primary purpose of AAC devices is to provide treatment for severe dysarthria, apraxia, and aphasia and to improve the health outcomes of individuals with these severe communication disabilities. AAC devices provide a 'meaningful contribution' to the treatment of these severe communication disabilities, enabling individuals both to overcome the adverse effects of these severe communication impairments, and to meet the communication needs arising in their daily activities. *See* MCM § 2100.2.

Second, as explained in Section 3, the speech-language pathology assessment process considers AAC interventions only after a determination has been made that treatment related to improved natural communication methods will not be effective. Thus, when an AAC device is recommended for an individual, there is no medically effective alternative form of treatment that will be of benefit.

Finally, effective communication is essential for an individual to successfully negotiate routine daily activities, particularly when other physical or mental disabilities are present in addition to a severe communication impairment. In order to obtain medical care for those other conditions, AAC devices provide an effective way to communicate about these topics and access effective treatment for any other health conditions. This is an example of providing, in the words of Dr. Kang, 'intermediate outcomes -- with known links to desired outcomes.' As explained in Section 3, severe communication disabilities can disrupt every facet of an individual's life.[9] Also, because individuals with severe communication disabilities may not be able to accurately

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9 As reported in the example of Celia Cooper, the adverse impacts of her anarthria affected her relationship with her husband, family and friends; her role as a home-maker; her ability to be left alone or to go out into the community alone; and her mood.

express symptoms or effectively respond to care providers, medical care can be delayed or misdirected.[10]

2. AAC Devices are not Experimental

Under the Medicare statute, an item or service is considered experimental when it 'is not yet generally accepted, is rarely used, novel or relatively unknown.'[11] An item or service is no longer considered experimental when it 'has come to be generally accepted by the professional medical community as an effective and proven treatment for the condition for which it is being used.'[12] AAC devices are not experimental. The general medical community views AAC devices as an effective and proven treatment for severe communication disabilities.[13]

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10 For example, absent use of an AAC device, an individual's broken bones may not be discovered for days *(In re: Keith C., 1991)*. Infections may not be identified and treated until they become extremely severe *(e.g, In re: Anonymous, 1988)*. Sources of pain may not be localized and appropriate treatments begun in a timely manner, as was discussed in Section 3 in regard to Ruth Sienkiewicz-Mercer. *(See also, In re: Shannon, 1990)*. Also, for some individuals, the inability to communicate itself is so frustrating and isolating as to give rise to depression that must be treated as a mental health impairment. Celia Cooper, for example, was described by her SLP as 'an outgoing, warm woman, but cries easily and is understandably depressed by her total inability to communicate.' *(See also In re: Larry N, 1993; In re: Liang-Kuang C., 1987)* As to the latter point, the professional literature notes:

> As is true in the case of other individuals with disabilities, psychological intervention may facilitate the rehabilitation process. Without the use of [AAC devices], however, psychological services would be unavailable to the majority of anarthric and dysarthric patients. *The devices do not merely facilitate the therapeutic process; they enable it to occur.*

(Crawford, 1987)(emphasis supplied).

11 Enclosure # 2 to Intermediary Letters No. 77-4 & 77-5, reprinted in [1976 Transfer Binder], CCH Medicare and Medicaid Guide, § 28,152 (1976). This definition also has been adopted by other health benefits programs, such as Medicaid. *See Rush v. Parham*, 1980; *Weaver v. Reagen*, 1989; *McLaughlin v. Williams*, 1992; *Miller v. Whitburn*, 1993; *Smith v. Rasmussen*, 1999).

12 *Id.*

13 The 'general medical community' for AAC intervention includes SLPs, the clinical professionals most directly responsible for treatment of severe communication disabilities. Since 1981, the American Speech-Language-Hearing Association has recognized AAC intervention as an accepted methodology that is within the scope of practice for SLPs (ASHA, 1981; 1991). The acceptance of AAC intervention among speech-language pathology professionals is further demonstrated by the numerous professional standards and policy statements that ASHA has developed for AAC intervention, (ASHA 1989, 1996, 1997), as well as the establishment of AAC-focused specialty societies, including: the International Society for AAC (ISAAC),

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The clinical professionals who provide other rehabilitation services to and who advocate for individuals with severe disabilities also recognize AAC interventions that enable effective communication as essential treatment tools .[14] Neurologists, as the physicians most directly responsible for managing the care of individuals with ALS, recognize AAC intervention as the appropriate standard of care for individuals who have developed severe dysarthria or anarthria secondary to ALS. (Sufit 1997, Mitsumoto, Chad, & Pioo 1998). As described in greater detail in Section 3, SLPs recognize AAC intervention as the appropriate standard of care for individuals with severe dysarthria, apraxia, and aphasia, regardless of etiology. In addition, the American Medical Association's, 'Guidelines for the Use of Assistive Technology: Evaluation, Referral, Prescription' incorporate AAC interventions as treatment options that must be considered for these individuals. (AMA, 1994).

The general acceptance of AAC interventions by the professional medical community is further demonstrated by the volume of research and clinical practice research that has been published in peer-reviewed journals.[15] AAC interventions also are a common seminar topic at continuing professional education conferences sponsored by international, national, regional,

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established in the mid-1980s; a United States national chapter, USSAAC; an ASHA AAC Special Interest Division; and an AAC Special Interest Group within RESNA, the Rehabilitation Engineering and Assistive Technology Society of North America. ASHA, USSAAC and RESNA are among the organizations on whose behalf this Formal Request is being submitted.

14 In 1986, ASHA, the American Association on Mental Retardation, American Occupational Therapy Association, and American Physical Therapy Association and other organizations formed the National Joint Committee for the Communicative Needs of Persons with Severe Disabilities, to promote research, demonstration and education efforts directed to helping individuals with severe disabilities to communicate effectively. In 1992, this consortium produced 'Guidelines for Meeting the Communication Needs of Persons with Severe Disabilities,' intended to educate professionals in all of these disciplines of about the fundamental importance of providing an effective means of communication, including, as necessary, AAC interventions, to individuals with severe disabilities. These guidelines identify the core areas of knowledge and skill these professionals must possess, including AAC interventions, in order to provide effective treatment to these individuals. (ASHA, 1992).

15 A sub-set of this professional literature is reproduced in Appendix II. Ongoing AAC intervention research is funded by the National Institutes of Health, the National Institute of Deafness and Other Communication Disorders (Beukelman & Ansel 1995), as well as by the Department of Veterans Affairs (NeuroReport, 1998), and the National Institute on Disability and Rehabilitation Research. For more than a decade, NIDRR has supported an AAC Rehabilitation Engineering Research Center, whose research activities currently are being coordinated by David Beukelman, Sarah Blackstone, and Kevin Caves, who all were significant contributors to the preparation of this Formal Request.

state and local organizations, including USSAAC, ASHA, RESNA, and UCPA. In addition, AAC interventions are the subject of numerous books and treatises used by practicing professionals. They are also used as teaching aids in both undergraduate and graduate level courses in pre-professional training programs for SLPs and other disciplines which provide treat individuals with severe disabilities.

3. AAC Devices Are Cost Effective And Appropriate

Dr. Kang stated that to support coverage, HCFA seeks to identify the patients for whom the item or service is appropriate, the settings in which it is appropriately provided, and the professionals who are appropriate to provide it. As explained in Section 3, there are an estimated 47,000 Medicare beneficiaries with dysarthria, apraxia, and aphasia at a level of severity sufficient to require use of AAC devices. These individuals are given an assessment by an SLP and, at times, by other relevant professionals, such as an occupational or physical therapist. These assessments are conducted according to well-established data-gathering and decision making procedures and yield recommendations for specific AAC devices, and as necessary, accessories, from one of the three categories of AAC devices.

SLPs conduct functional assessments of an individual's ability to meet the communication needs arising in the course of daily activities. They recommend AAC interventions only when a) some type of treatment is necessary to achieve that goal; and b) treatment intended to improve natural speech methods will not be sufficient. In addition, the assessments are conducted independent of any AAC device vendor or supplier and are then submitted to an individual's treating physicians for review. AAC assessments, as well as the subsequent training and support for AAC device usage, are not setting-dependent. These tasks may be conducted at the individual's home or in a professional office setting.

The appropriateness of AAC devices also can be measured by the existing Medicare standards for 'reasonableness.' According to Medicare guidance, the reasonableness of an item or device is based on the following factors:

1. Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?

2. Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?

3. Does the item serve essentially the same purpose as equipment already available to the beneficiary?

MCM, § 2100.2. AAC devices satisfy all of these 'reasonableness' criteria. First, as discussed above and in greater detail in Section 3, the assessment and clinical decision making process related to AAC intervention is sequential: an SLP will consider AAC interventions only after the assessment determines that AAC treatment is needed to enable the individual to meet the communication needs arising in daily activities *and* that SLP treatment intended to improve natural communication methods will not be sufficient to achieve that goal. Thus, AAC interventions are recommended and prescribed only when there is no medically appropriate or realistically feasible alternative pattern of care.[16]

Because of the nature of severe communication disabilities, the 'substantial increases' achieved by individuals who use AAC devices incorporate a wide range of functional communication abilities. Such range is identical to the range expected for all recipients of Medicare funded speech-language pathology services, *i.e.*, AAC device use enables individuals to achieve the functional outcomes that are associated with Medicare-funded SLP services:

- to give a consistent 'yes' or 'no' response;
- to demonstrate a competency in naming objects using auditory/spoken cues;
- to communicate basic physical needs and emotional status;
- to communicate self-care needs;
- to receptively and expressively use a basic spoken vocabulary and/or short phrases;
- to engage in social communicative interaction with immediate family or friends;
- to carry out communicative interactions in the community; or
- to regain conversational language skills.

MIM § 3905.3, MHM§ 446(a)(1)(A).[17]

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16 Indeed, for individuals with progressive impairments, the recommendation for an AAC device often will be preceded by a period of SLP treatment directed to natural communication methods. However, due to the progression of the impairment, those communication methods are no longer sufficient to enable the individual to meet his daily communication needs.

17 As can be seen from this list of functional outcomes, and the manner in which AAC needs are assessed, *i.e.*, as a seamless part of an SLP services assessment, the provision of all Medicare-funded SLP services necessarily focuses on improved communication abilities in the broadest sense. For example, Medicare has no coverage limitation related to communication of specific topic information, such as health-related issues. For AAC devices, no content- or context-based limitation would be appropriate, a point discussed in the conference call with Medicare staff on June 17, 1999.

SLP research has demonstrated that health-related issues are no more frequent a topic of conversation than others among older individual (Stuart *et al.* 1993), or among individuals who use AAC devices. (Beukelman, Yorkston, Poblete, & Naranjo, 1984). Moreover, there is no established health related lexicon, such as an agreed upon list of medically-related words; there is no connection

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B. AAC DEVICES MEET THE MEDICARE REGULATORY DEFINITION OF DME

This Formal Request seeks classification of AAC devices as DME. 42 U.S.C. § 1395x(n). DME is defined as equipment furnished by a supplier or home health agency that has the following four characteristics:

1. can withstand repeated use;

2. is primarily and customarily used to serve a medical purpose;

3. generally is not useful to an individual in the absence of illness or injury; and

4. is appropriate for use in the home.

42 C.F.R. § 414.202. Based upon the treatment role of AAC devices described in Section 3, and the specific device characteristics described in Section 5, we submit that AAC devices meet all of these criteria.

Peggy Locke, President of the Communication Aid Manufacturers Association, stated in a recent letter:

> AAC devices allow their users to achieve [their communication] goals by providing a functional substitute for body organs and structures that are necessary for the production of speech but which are non-functioning or mal-functioning due to illness, injury, disease or condition. Another way to describe the purpose of AAC devices is as a functional by-pass of these non- or mal-functioning body structures, *i.e.*, they allow the AAC device user to express a thought (message) as speech, by by-passing the nerves, muscles, and organs of speech which, due to impairment, make natural speech ineffective. The AAC device is the by-pass. Viewed in

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> between the characteristics and capabilities of AAC devices and specific words; and there is no effective way to 'limit' the content of speech produced by AAC devices. No currently available AAC device offers fixed, pre-set vocabulary; rather, all devices, in every category, allow for the user to select the vocabulary. In addition, any device that allows a user to construct vocabulary by spelling, whether the speech output is digitized or synthesized, automatically offers access to the entire English language. Lastly, no other health-focused funding programs which, like Medicare, require proof of 'medical necessity,' incorporate content or use-context limitations in their criteria. New York Medicaid expressly rejected such limitations for AAC devices in 1988, and 1991 (*In re: Andrew Szczygiel*, 1988; New York Department of Health, 1991), and it is not incorporated in other states' AAC device coverage criteria. (California, 1995; Indiana, 1992; Maine, 1992; Michigan, 1994; Ohio, 1993).

> this way, AAC devices provide the same benefits and serve the same functional purposes as power wheelchairs. A person with quadriplegia or other severe mobility impairment is unable to implement the desire to move from place to place. With a power wheelchair, however, the person is able to by-pass his or her no-working spinal column or other non- or malfunctioning body structures to accomplish the goal of mobility.
>
> Stated more simply, every aspect of AAC device design, manufacture, marketing and sales is directed exclusively to people with severe communication disabilities. Knowledge of the unmet needs of people with disabilities drives the AAC device design process so that new devices and related products can meet those needs. AAC device marketing is directed exclusively to people with severe communication disabilities. And, the augmentative communication devices and related products manufactured and distributed by CAMA members have been and continue to be sold exclusively for use by persons with severe speech and language disabilities.

Letter dated October 23, 1999 to Lewis Golinker, from Peggy Locke, attached at Appendix III, Tab A.

The Medicare program has established seven payment categories for DME. 42 U.S.C. § 1395m; 42 C.F.R. §§ 414.220-.232.[18] AAC devices qualify under the first category as 'routinely purchased' items. *See* 42 U.S.C. § 1395m(a)(2)(A)(ii); *see also* 42 C.F.R. § 414.220(a)(2). The Communication Aid Manufacturers Association, whose members include almost every company that manufactures and distributes AAC devices in the United States, recently surveyed its members to learn of their rental and sales practices. The result of that survey, reported by CAMA president Peggy Locke, was that:

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18 Medicare regulations require carriers to determine fee schedules for the following classes of equipment and devices:

> (i) Inexpensive or routinely purchased items;
>
> (ii) Items requiring frequent and substantial servicing;
>
> (iii) Certain customized items;
>
> (iv) Oxygen and oxygen equipment;
>
> (v) Prosthetic and orthotic devices;
>
> (vi) Other durable medical equipment (capped rental items); and
>
> (vii) Transcutaneous electrical nerve stimulators (TENS).

42 C.F.R. § 414.210

> I am able to report that with almost no exceptions, AAC devices are acquired by their users by sale. This represents far more than the 75 % of all devices; it is almost 100 percent of all AAC devices. The availability of long-term rental of AAC devices is the exceedingly rare exception; far more common is a limited rental option of 30-90 days, which is intended solely to permit trial periods. In addition, the CAMA members reported that this practice has been consistent throughout their existence as AAC device manufacturers and distributors.

Letter dated October 23, 1999 to Lewis Golinker, from Peggy Locke, President, Communication Aid Manufacturers Association, attached , attached at Appendix III, Tab A.

Assigning AAC devices to the 'routinely purchased DME' payment category is consistent with all the information herein.

C. State Medicaid Coverage Of AAC Devices

All state Medicaid programs cover AAC devices, with approximately half of all state Medicaid programs classifying AAC devices as items of DME. Of these, eight programs utilize a definition of DME that is identical or substantially identical to the Medicare DME definition and also classify, cover, and pay for AAC devices under the DME benefit. **Table 5** lists these states and identifies their Medicaid DME definitions. Private health insurers also generally cover AAC devices as within policy or benefits plans' DME benefit.

Table 5: State Medicaid Coverage Of AAC Devices

State	[illegible]
Illinois	Dept. of Public Aid, Medical Assistance Provider Manual. §II-M-3. M-201.2 (Dec. 1992).
Indiana	470 IAC 1-7, § 27(g), at p. A2-49 (Oct. 1, 1994).
Iowa	Iowa Dept. of Human Serv., Coverage & Limitations. Medical Equipment and Supply Dealer. Chapt. E, page 2(b)(Jan 1, 1994), *see also* Iowa Medicaid Augmentative Communication Device Funding Criteria, Medical Equipment and Supply Dealer Manual. Chapt. E, p. 12, § D (Oct. 1, 1988).
New Jersey	N.J. Medicaid, Medical Equipment and Supplies Supplier Manual, Sub-Chapt. I, § 1.2 (Nov. 1979).
New York	18 N.Y.Code of Rules and Regulations, § 505.5(a)(1).

North Dakota	N.D. Dept. of Human Serv., Medical Assistance Program, DME Supplies and Guidelines, § 1.
South Carolina	S.C. Medicaid Home Health Serv. Manual, at p. 2-1.
Wisconsin	Wisc. Admin. Code, HSS, § 101.03(50).

Both 'dedicated' AAC devices and AAC devices that are 'computer-based' are appropriately classified as DME. Although computers in general are not considered DME, when 'the primary use of the computer will be as [an individual's] communication device,' there is general acceptance that these devices ***are*** DME. (USSAAC, Medicaid Model AAC Device Coverage Policy, 1995). All state Medicaid programs cover both dedicated and computer-based AAC devices, and at least seven states make express reference to computer-based AAC devices in their AAC coverage criteria. Two states, Delaware and Louisiana, have formally adopted the Medicaid Model Policy, referenced above. The other five states are identified in TABLE 6.

TABLE 6: STATE MEDICAID AAC DEVICE LEVERAGE CRITERIA INCLUDING COMPUTER-BASED DEVICES

Indiana	'If authorization is requested for a computer or computerized device, the intended use of the computer or computerized device must be compensation for loss or impairment of communication function.'	470 Indiana Admin. Code § 5-8-12(q)(5)
Maine	'Includes: methods that use communication boards, charts and mechanical or electrical aids, or computerized devices.'	Maine Medical Assistance Manual, § 60, App. 3, § XI(A)
New Hampshire	'Any device which results in improved communication for persons with severe communication disabilities. AAC equipment may include, but is not limited to the following: picture/symbol/letter/word board/book/wallet; electronic device; computer hardware, software, adaptive input/output devices; mounting hardware; environmental control devices; telecommunications equipment.'	New Hampshire Medicaid AAC Criteria (Definitions)

New York	'These components include, but are not limited to, communication devices, manual signs and communication strategies. Communication devices may be comprised of a primary unit such as a computer, dedicated device, manual board, electrolarynx, or amplifier and accessories which may include but are not limited to output peripherals such as printers, communication application programs, language symbols, interfaces, overlays, cables and mounts.'	New York Dept. Of Health, Guidelines: Augmentative and Alternative Communication Systems (Definitions)
Ohio	'Personal computers and related hardware, unless components of a personal-computer based systems that has been adapted for use as a communication device.'	Ohio Admin. Code, § 5101:3-10-24(K)(3)

D. Medicare ALJ Decisions Recognizing Coverage For AAC Devices

In five of the six known Medicare AAC administrative law judge (ALJ) decisions, where non-coverage of AAC devices was challenged, the ALJ approved the requested AAC device under the Medicare DME benefit. The sixth Medicare AAC ALJ decision awarded the device but concluded the device was within the Medicare prosthetic device benefit. Table 7 lists those decisions, which also are included in Appendix III at Tab A.

Table 7: Medicare AAC ALJ Decisions

Case Name	
In Re: Donald S.	Dkt No. 000-89-3072 (Social Security Admin. Office of Hrgs & Appeals October 1, 1999)
In re: Bernadine A.	Dkt No. 000-86-0336 (Social Security Admin. Office of Hrgs & Appeals April 27, 1999)
In re: Celia C.	Dkt No. 196-14-0195 (Social Security Admin. Office of Hrgs & Appeals December 2, 1998)
In re: Richard A.	Dkt No. 000-06-0110 (Social Security Admin. Office of Hrgs & Appeals March 24, 1997)
In re: Blanche B.	Dkt No. 000-24-0399 (Social Security Admin. Office of Hrgs & Appeals May 8, 1995)

E. FDA Status Of AAC Devices

This subsection addresses three issues identified in the April 27, 1999 *Federal Register* notice which must be addressed in Formal Requests for National Coverage Decisions: 1) the FDA classification of AAC devices: 2) the proposed Medicare benefits classification for AAC devices; and 3) the proposed reimbursement category for AAC devices. Each of these points is discussed below.

1. FDA Classification Of AAC Devices as Medical Equipment

Under the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 *et. seq*, the term 'device' is defined as:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is -
>
> (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. §321(h). FDA regulations define 'device family' as:

> a group of one or more devices manufactured by or for the same manufacturer and having the same:
>
> (i) Basic design and performance characteristics related to device safety and effectiveness,
>
> (ii) Intended use and function, and
>
> (iii) Device classification and product code.
>
> Devices that differ only in minor ways not related to safety or effectiveness can be considered to be in the same device family. Factors such as brand name and common name of the device and whether the devices were introduced into commercial distribution under the same 510(k) or premarket approval application (PMA), may be considered in grouping products into device families.

21 C.F.R. § 803.3(e).

The FDA recognizes AAC devices as medical 'devices' within the 'physical medicine devices intended for human use' category. 21 C.F.R. §§ 890,3700, 890, 3710. The FDA further sub-divides AAC devices as two types of devices: powered communication systems and non-powered communication systems. The FDA classifies powered communication systems as Class II[19] devices and identifies them as:

> an AC- or battery-powered device intended for medical purposes that is used to transmit or receive information. It is used by persons unable to use normal communication methods because of physical impairment. Examples of powered communication systems include the following: a specialized typewriter, a reading machine, and a video picture and word screen.

21 C.F.R. § 890.3710. The FDA classifies nonpowered communication systems as Class I devices and identifies them as:

> a nonpowered communication system is a mechanical device intended for medical purposes that is used to assist a patient in communicating when physical impairment prevents writing, telephone use, reading, or talking. Examples of nonpowered communications systems include an alphabet board and a page turner.

21 C.F.R. § 890.3700. This Formal Request for AAC Device National Coverage Decision addresses only the family of medical devices in the 'powered communication device' category.

II. CURRENT MEDICARE COVERAGE STATUS FOR AAC DEVICES

Medicare currently does not cover AAC devices. Some time during the late 1980s, HCFA issued a National Coverage Decision (NCD), which appears as part of the 'DME Reference List.'[20] The NCD states that coverage for Augmentative Communication Devices is

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19 The FDA has issued additional guidance regarding 'powered communication devices.' Pursuant to the Food and Drug Administration Modernization Act of 1997, on January 21, 1998, the FDA provided notice in the Federal Register that powered communication systems were among the 'Class II' medical devices 'that [do] not require a report under section 510(k) of the act (generally referred to as a premarket notification or '510(k)') to provide reasonable assurance of safety and effectiveness.' 63 *Fed. Reg.* 3142, 3143 (Jan. 21, 1998). The exemption granted to these AAC devices was based on the FDA's determination that 'a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device.' *Id.*

20 The DME Reference list contains all DME coverage determinations discussed in the DME portion of the Coverage Issues Manual ('CIM'). In the case of equipment categories that have been determined by HCFA to be covered under the DME benefit, the list outlines the conditions of coverage that must be met if payment is to be allowed for the rental or purchase of the DME by

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denied because such devices are convenience items that are not primarily medical in nature as defined in section 1861(n) of the Social Security Act. CIM § 60-9.

At the time we believe HCFA developed the NCD, there was no information from any reliable source that supported HCFA's conclusion that an AAC device did not provide treatment for expressive communication impairments. Likewise, there was no basis at that time, or ever, to conclude AAC devices served as a mere convenience to the individuals who require them. To the contrary, by the mid-to-late 1980s, there was an existing body of professional literature describing AAC intervention, as well as professional statements of policy and practice guidelines, a wide range of AAC devices, and a foundation of coverage practices and policies among federal and private payors. The types of information available in the 1980s mirror the information about AAC intervention available today and on which this Formal Request is based.

A. History Of The Medicare Augmentative Communication Device National Coverage Decision

It is estimated that HCFA developed the Medicare Augmentative Communication Device NCD between late-1986 and 1989. We support this estimate with the following information. First, there was no reference to AAC devices on a 1984 Medicare 'DME Screening List,' which appears to be the pre-cursor of the 'DME Reference List.'[21] Second, on October 15, 1986, the HCFA Region V office wrote to a fiscal intermediary about Medicare AAC device coverage, but no reference was made to any applicable Medicare guidance about AAC devices.[22] Third, the NCD appeared in the August 21, 1989 *Federal Register* as part of a general disclosure of existing Medicare National Coverage Decisions. 54 *Fed.Reg.* 34,555, 34,597 (Aug. 21, 1989). However, no additional information about the development of or the basis for this NCD was provided in the *Federal Register*. There are no records that explain its history, and HCFA staff

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a particular patient, or cross-refers to another section of the manual where the applicable coverage criteria are described in more detail. The list includes a brief explanation of why certain equipment categories cannot be covered and is updated periodically to reflect any additional national coverage decisions that HCFA makes with regard to other categories of equipment. CIM §60-9.

21 'Screening List for Durable Medical Equipment,' Medicare Carriers Manual, Chapter II, Coverage Issues Appendix (1984), reprinted in K. Reeb, *Procurement of Durable Medical Equipment Under the Medicare Part B Program* (Washington, D.C.: Electronics Industries Foundation June 1985)(unpubl. report).

22 Letter dated October 15, 1986 to Stephen T. Crickmore, Director, Medicare Part A, Blue Cross and Blue Shield of Indiana. Only the first page of this letter exists. A Freedom of Information Act request was sent to HCFA to try to locate a complete copy of this letter, but no records were found. Letter dated August 24, 1999 to Lewis Golinker, from Phillip Brown, Director, HCFA Division of Freedom of Information.

acknowledge that the decision is 'poorly documented.' (email correspondence with S. Olshan, 8/18/99). HCFA staff have stated that the agency has no records related to this guidance.[23]

Among the information that does not exist is what initially prompted HCFA to develop this NCD; when was it written; what information was considered; and who was involved with its issuance. Notwithstanding these limitations, some information about the AAC Device guidance does exist, and this is provided below. HCFA's own attempts to trace the foundation and development of the Augmentative Communication Device NCD have been unsuccessful. In 1998, HCFA staff searched its records and reported that none existed.[24] HCFA undertook the additional searches in 1999, which also yielded no records.[25] Little is known about this AAC Device NCD except that HCFA staff developed the NCD without input from any of the individuals who prepared this Formal Request or from any of the organizations on whose behalf this Formal Request is being submitted.

Less is known about the information HCFA staff considered in developing the Augmentative Communication Device NCD. HCFA acknowledged that it did not conduct an extensive medical literature search nor did it seek the advice of knowledgeable medical professionals in developing this guidance -- two procedures it was required to undertake in developing NCDs as set forth by the Medicare Act's 'reasonable and necessary' provision. *See* 42 U.S.C. § 1395y(a)(1).[26] However, HCFA staff reported that these procedures were not

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23 Letter dated August 24, 1999 to Lewis Golinker, from Phillip Brown, Director, HCFA Division of Freedom of Information; letter dated July 8, 1998 to Elizabeth Carder, from Philip Brown, Director, HCFA Division of Freedom of Information and Privacy; response by Grant Bagley, M.D., to Plaintiff's First Set of Interrogatories, filed in *Rhode Island Disability Law Center v. U.S. Department of Health & Human Services*, No. 98-415T (D.R.I.).

24 Letter dated July 8, 1998 to Elizabeth Carder, from Philip Brown, Director, HCFA Division of Freedom of Information and Privacy.

25 Response by Grant Bagley, M.D., to Plaintiff's First Set of Interrogatories, filed in *Rhode Island Disability Law Center v. U.S. Department of Health & Human Services*, No. 98-415T (D.R.I.); Letter dated August 24, 1999 to Lewis Golinker, from Phillip Brown, Director, HCFA Division of Freedom of Information.

26 An April 1987 *Federal Register* notice delineates the process by which HCFA should determine what constituted 'reasonable and necessary' under the Medicare statute and then develop NCDs:

> Most of the 'reasonable and necessary' coverage issues referred to us can be decided on the basis of the statute, regulations and policy statements. Some issues arise that we cannot resolve without seeking additional professional medical expertise. Included are issues for which questions of the safety and effectiveness of an item or service, or its common acceptance by the medical profession, cannot easily be resolved. These questions may concern either new or unusual items or services, or items

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followed for NCDs for items falling under the Medicare DME definition, such as AAC devices. *See* 42 U.S.C. § 1395x(n).

Grant Bagley, M.D.,[27] a former HCFA official, explained in a Medicare appeal several years ago that no medical literature review ever was conducted, and no staff-prepared background paper exists for AAC devices. In response to an inquiry related to another item on the DME Reference List, which, like the AAC device, is based on the Medicare DME definition, Dr. Bagley stated:

> QUESTION: When and for what NCDs [National Coverage Decisions] did you first use the April 1987 process in making any NCD?
>
> RESPONSE: The April 29, 1987 Federal Register Notice described the existing procedures for making national coverage decisions under section 1862(a)91)(A) of the Social Security Act. . . . NCDs that are made based on provisions of the Social Security Act other than section 1862(a)(1)(A) are not subject to the process described in the Federal Register Notice. Thus, provisions such as

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> and services that are believed to be outmoded and no longer reasonable and necessary.

52 Fed. Reg. 15,660, 15,661-62 (April 27, 1987).

The *Federal Register* notice also identified the methods HCFA staff should employ to obtain medical and scientific advice in developing NCDs:

> When medical advice is needed in order to evaluate a coverage question, the issue is referred within HCFA to the Bureau of Eligibility, Reimbursement and Coverage (BERC). Staff in BERC conduct a medical literature search, determine the status of any FDA action, and prepare a background paper on the item or service.
>
> The background paper stresses the information obtained from the medical literature search and administrative aspects of the issue. . . .

52 Fed. Reg 15,662.

The other methods listed included referral of the issue to a HCFA Physicians Panel, and/or to the Public Health Service, Office of Health Technology Assessment (OHTA). *Id.*

27 Former Director of the HCFA Coverage Analysis Group, Office of Clinical Standards and Quality

the definition of DME made under section 1861(n) would not be subject to the '1987 process.'[28]

B. Extensive Medical & Professional Information About AAC Intervention Strategies Was Available During The Development Of The NCD

It is impossible to speculate whether HCFA would have issued the Augmentative Communication device NCD in its present form had it prepared a professional literature-based staff background paper, but it is without question that by 1989, there was a substantial body of professional medical literature addressing the policy and practice related to AAC intervention and the use of AAC devices. In addition, during the time HCFA issued the NCD, a wide range of AAC devices was available with capabilities comparable to those which are in use today. Moreover, at that time most third party payors including Medicaid, private insurance providers, CHAMPUS (now Tri-Care), and the Veterans Administration (now the Department of Veterans Affairs), reimbursed for AAC devices as either DME or prosthetic devices.

As discussed above in Section 3, researchers at the Mayo Clinic first recognized the role of AAC intervention as treatment for dysarthria in the 1960s (Darley, Aronson & Brown, 1969a; 1969b; 1975). Subsequent AAC intervention research, clinical practice, and professional literature are all built upon this foundation. During the 1970s, AAC intervention emerged as an area of specialization within the practice of speech-language pathology, and American and European peer-reviewed journals contained numerous articles on the subject (Zangari, Lloyd & Vicker, 1994).[29]

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28 Response by Grant Bagley, M.D., to Plaintiff's First Set of Interrogatories, filed in *Rhode Island Disability Law Center v. U.S. Department of Health & Human Services*, No. 98-415T (D.R.I.).

29 The first text-books with two or more chapters related to AAC (Lloyd, 1976; Schiefelbusch & Lloyd, 1974) books devoted entirely to AAC (Copeland, 1974; Scheifelbusch, 1977; Vanderheiden & Grilley, 1976; Vicker, 1974), and other books documenting successful clinical applications of AAC strategies also were published during this period (Fristoe, 1975; Silverman, McNaughton & Kates, 1978; Vicker, 1974).

This period saw the development of the first courses devoted solely to AAC intervention, as well as increased use of AAC texts in other disability-related courses, such as those directed to cerebral palsy and other neurologic conditions. Also during the 1970s, there was a marked increase of presentations describing AAC intervention research and clinical techniques at professional conferences. (Fristoe & Lloyd, 1977; McDonald, Murphy & Huskey, 1972; McNaughton & Kates, 1974; K. van Hook & P. Stohr, 1973). Development of professional policy statements also began in the 1970s. In 1978, the American Speech-Language-Hearing Association (ASHA) formed an Ad Hoc Committee on the Communication Processes of Non-Speaking Persons, (Zangari, Lloyd and Vicker, 1994), which led to the formal acknowledgement of AAC intervention as within the scope of speech-language pathology in August 1981. (ASHA, 1981, 1991).

Developments related to AAC professional literature, practice, and policy continued throughout the 1980s. AAC transitioned from a 'pioneering phase,' in which successful AAC interventions were viewed as the exception rather than the rule, to one of 'public policy,' where AAC devices are accepted as appropriate clinical intervention for individuals with severe communication disabilities. Further, payment for AAC devices became based on practice guidelines, rather than ad-hoc decision making. (Beukelman, 1990; Beukelman & Mirenda, 1998). The 1980s also heralded the birth of several organizations devoted to AAC issues including the International Society for Augmentative and Alternative Communication (ISAAC) in 1983.[30] Publication of AAC research findings and clinical practice techniques continued throughout the 1980s in a variety of peer-reviewed journals, textbooks, and newsletters.[31] By 1987, the volume of professional literature had expanded to permit ISAAC to publish a 'Core Reference List' for professionals interested in clinical practice in AAC (Windsor & Lloyd, 1987). The entry into a 'public policy' phase for AAC intervention also coincided with the development of guidelines for the field, *i.e.*, 'best practices' recommendations for AAC assessment, intervention, delivery.[32]

The AAC devices available at that time included devices that produced digitized speech and those that produced synthesized speech, permitting multiple methods of language (message) formulation and multiple methods of access.[33]

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30 The United States Society for Augmentative and Alternative Communication (USSAAC), the United States national chapter of ISAAC, is one of the organizations that is submitting this formal request.

31 Publication sources include the ISAAC-published peer-reviewed journal, *AAC* (currently in its 15th volume), AAC focused newsletters such as the ISAAC *Bulletin* and *Augmentative Communication News*, published by Sarah Blackstone, Ph.D., one of the authors of this Formal Request, and textbooks and treatises, including *Augmentative & Alternative Communication: An Introduction*, edited by Sarah Blackstone and published by ASHA in 1986, and Blackstone, Cassatt & Bruskin, *Augmentative Communication: Implementation Strategies*, published by ASHA in 1988.

32 Zangari, Lloyd and Vicker, 1994, identify the many proposals that were circulated in the professional literature during this period. Among them were ASHA's Policy Statement on Nonspeech Communication, which formally recognized AAC interventions as within the scope of practice of SLPs (ASHA, 1981), and a statement of competencies for SLPs providing AAC intervention services, developed by ASHA (ASHA, 1989).

33 'Not only were more dedicated communication aids available during the 1980s but there were significant improvements in sophistication, performance and dependability.' (Zangari, Lloyd, & Vicker, 1994). AAC devices of that period used DEC Talk, still the industry standard speech-synthesizer; some had dynamic displays; some relied on MinSpeak; and some permitted a wide range of alternate access methods, all features of currently available AAC devices. (Zangari, Lloyd & Vicker, 1994). Some models developed during that period are still marketed today. An example is the Say-It-All, by Innocomp. Other devices, such as the Touch Talker and Light

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Talker by the Prentke Romich Company were introduced during the 1980s and are the predecessors of the Vanguard, Liberator and Delta Talker, all currently available devices.

The number of AAC devices available and being introduced during that period was sufficiently great that charts identifying each device and describing relevant characteristics were developed to aid SLPs make appropriate recommendations of specific devices. (Kraat & Sitver, 1983)(describing characteristics of 44 AAC devices). A text describing and explaining the significance of various device features also was written during this period. (Fishman, 1987).

SECTION 5: TYPES OF AAC DEVICES

OVERVIEW

A critical component of the AAC device assessment process is to match the amount and kind of language in the user's brain to the amount and kind of language available in a particular AAC device so the individual can generate language as efficiently and effectively as possible. A proper match permits the individual to use the AAC device to communicate his or her thoughts and ideas and thereby meet the communication needs arising in daily activities. From a technological perspective, AAC devices have unique features that allow the user to generate messages as efficiently as possible. Selecting the appropriate device for an individual requires an understanding of the technology and the individual's strengths. Section 3 presented information about the decision making process that leads to the appropriate selection of a device within one of the categories for individuals who need AAC devices, while this section describes the devices themselves.

Today's AAC devices offer a range of features that address the widely variable language requirements of individuals with severe communication impairments. Subsection I defines three categories of AAC devices that have distinct technological and functional characteristics, including:

- AAC devices with digitized speech output;
- AAC devices with synthesized speech output, which require message formulation by spelling and device access by physical contact direct selection techniques; and
- AAC devices with synthesized speech output, which permit multiple methods of message formulation and multiple methods of device access.

Subsection II describes the general characteristics or key features found in each, including:

- Methods of Displaying Language: Dynamic Display and Static Display;
- Methods of Storing and Retrieving Language: Levels and Encoding Strategies (numeric, letter, semantic); and
- Rate Enhancing Methods: Message Prediction.

Subsection III discusses the variety of device accessories that are medically necessary for the proper use of the devices, including:

- Switches/keyboard adaptation and selection (pointing) devices;
- Mounting systems;
- Carrying cases;

- Power accessories; and
- Software.

I. CHARACTERISTICS OF AAC DEVICES

AAC devices refer to a class of durable medical equipment that serves a common purpose: the treatment of the expressive communication impairments that interfere with a person's meaningful communication in current and projected daily activities. As is further explained in Section 3, individuals with severe dysarthria, aphasia, and apraxia who are unable to meet the communication needs that arise in the course of their daily activities through natural speech, gestures, and writing, use AAC devices to communicate. In addition, as was explained in Section 4, because AAC devices provide a viable means -- and will be the only means -- to achieve effective communication, they are a reasonable and necessary component of speech-language pathology treatment for these individuals.

An AAC device is incorporated into a treatment plan as a tool that enables an individual with a significant communication impairment to obtain, maintain, or regain communication capabilities. Such a device merges a variety of technologies that are specifically designed and configured to allow an individual to communicate independently for a variety of different reasons, across environments (home, medical settings, community, work), with familiar and unfamiliar partners, and over time. Selecting the appropriate device for an individual beneficiary requires an understanding of the technology as well as expertise in the types of speech and language impairments that interfere with functional communication. An SLP and other allied health professionals (*e.g.*, occupational therapist, physical therapist, rehabilitation engineer) as necessary conduct an assessment process (outlined in detail in Section 3), to recommend and confirm the most appropriate AAC device to enable an individual to meet his or her daily communication needs.

A. AAC Device Categories

A variety of AAC device designs/configurations currently exist, because no single device (or device category) can offer efficient and effective communication to all people with severe communication impairments and concomitant disabilities. The role of an SLP or a team of allied health professionals is to determine, through an evaluation, the key components of the technology that will best meet an individual user's needs. This process of systematic and objective evaluation and follow-up also safeguards against inappropriately underutilized or abandoned devices.

Based on their design characteristics, AAC devices appropriately are sub-divided into three categories:

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

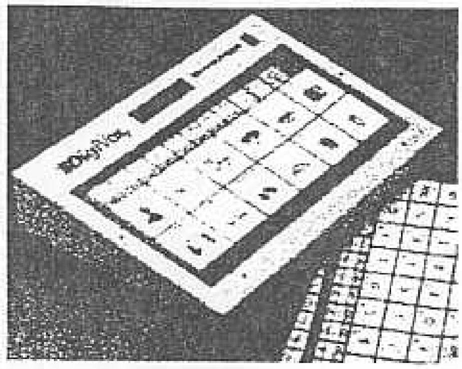
SLPs reference distinct clinical indicators to match these categories to the individual's profile of physical, cognitive, linguistic, sensory, and motor deficits and to the individual's communicative needs. These categories also are the basis for HCPCS coding suggestions in Section 6.

1. AAC Devices With Digitized Speech Output

AAC devices employ two principal means of speech production: digitized and synthesized speech. In terms of the qualitative aspects of the speech signal (pitch, resonance, and melody), digitized speech is more natural sounding than synthesized speech because it is a time sampled replication of actual human speech. Both digitized and synthesized devices produce speech that is highly intelligible (understandable) to the listener (Rupprecht, Beukelman & Vrtiska, 1995). Digitized speech output AAC devices represent a single category of AAC devices (Category #1). Digitized speech output essentially is natural speech that has been recorded, stored, and reproduced. Although digitized devices vary in physical dimensions, storage capacity and access methods, their fundamental components include a microphone, a series of filters, and a digital-to-analog converter. Thus, the reproduced speech output is a close replica of the original speech entry. The professional literature describes AAC devices with digitized speech as 'closed' systems because the device's entire capacity for speech output is limited to the words, phrases, or messages that have been pre-stored for the user, ideally by someone of the same gender, under the direction of the treating SLP. Digitized speech devices also are called 'whole message' systems, because they can provide the user with an entire phrase, sentence, or message that can be accessed by a single selection on an AAC device. Individuals who do not have the linguistic capacity to formulate messages independently; who have cognitive or language impairments; and who are unable to generate messages through spelling and/or word-by-word message development (such as those with severe aphasia due to cortical stroke typically require a 'whole message' digitized AAC device.

The amount of language that can be stored in a digitized speech AAC device varies greatly. The memory capacity ranges from a minute or two an hour or more of speech. Examples of digitized speech devices are displayed in FIGURE 2.

FIGURE 2: DIGITIZED SPEECH AAC DEVICES



MESSAGE MATE

Words+, Inc.

DIGIVOX

DynaVox Systems, Inc.

TABLES 8-11 below lists examples of digitized speech AAC devices. The tables are categorized by recording time and grouped according to the modifiers in the proposed NCD.

TABLE 8: DIGITIZED SPEECH OUTPUT DEVICES -- LESS THAN 4 MINUTES

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
ActionVoice 2 Enabling Devices	2.0	1	ACTV	$595
BigMack AbleNet, Inc.	0.3	1	1-BM	$86
Cheap Talk 8 Enabling Devices	0.6	1	1389	$200
Fifteen Talker The Attainment Company	2.0	1	ATT-15C	$489
Five Talker The Attainment Company	2.0	1	ATT-059C	$349
Hawk II Adam Lab, Inc.	2.0	2	Hawk II	$300
Hip Talker Enabling Devices	1.0	1	5016	$165
MessageMate 20/60 Words+, Inc.	1.0	1	MM20/60	$549
MessageMate 20/120 Words+, Inc.	2.0	1	MM 20/120	$749
One Step Communicator AbleNet, Inc.	.25	1	One Step	$99
SpeakEasy AbleNet, Inc.	4.3	1	1-SE3	$399
Step-by-Step Communicator AbleNet, Inc.	1.25	3	Step-by-Step	$149
Step Talk Switch Plate Enabling Devices	1.25	1	1355	$79

[illegible]				
Talk Back 24 Crestwood Company	4.0	1	3034	$599
Tech/Speak 2 x 32 Advanced Mulitmedia Devices, Inc.	2.1	2	X071232	$445
Tech/TALK 6 x 8 Advanced Mulitmedia Devices, Inc.	3.2	6	X07068	$395
Ultimate 4 Tash, Inc.	.25	1	2800	$99
VoicePal Adaptivations	1.0	1	VP-B	$325
VoicePal Max Adaptivations	1.0	1	VP-MAX-T60	$555
VoicePal Pro Adaptivations	1.5	1	VP-PRO-T90	$570

TABLE 9: DIGITIZED SPEECH OUTPUT DEVICES -- 4 TO 8 MINUTES

DEVICE/ MANUFACTURER				
6 Level Communicator Enabling Devices	4.0	6	2392	$245
Black Hawk Adam Lab, Inc.	4.0	4	Black Hawk	$475
Hand Held Voice Mayer Johnson Co.	6.0	Dynamic Display	H029A	$1495
MessageMate 40/300 Words+, Inc.	5.0	4	MM40/300	$1099
SpeakEasy AbleNet, Inc.	4.3	1	1-SE3	$399
Talk Back 24 Crestwood Company	4.0	1	3034	$599
Tech/Speak 4 x 32 Advanced Mulitmedia Devices, Inc.	4.1	4	X071432	$545
Tech/Speak 6 x 32 Advanced Mulitmedia Devices, Inc.	6.4	6	X071632	$645
Tech/TALK 8 x 8 Advanced Mulitmedia Devices, Inc.	4.25	8	X07088	$445
Tech/TALK 12 x 8 Advanced Mulitmedia Devices, Inc.	6.4	12	X070128	$645

TABLE 10: DIGITIZED SPEECH OUTPUT DEVICES -- 9 TO 16 MINUTES

DEVICE/ MANUFACTURER	(MINUTES)			(RETAIL)
Digivox2 DynaVox Systems, Inc.	16.0	48	Digivox2-16	$1600
EasyTalk The Great Talking Box Co.	16.0	4	EasyTalk-16	$1100

Hand Held Voice Mayer Johnson Co.	10.0	Dynamic Display	H029B	$1645
Macaw3 Zygo Industries	9.0	32	Macaw3	$2495
MessageMate 40/600 Words+, Inc.	10.0	4	MM40/600	$1299
SideKick Prentke Romich Company	11.5	1	SK	$1295

TABLE 11: DIGITIZED SPEECH OUTPUT DEVICES -- 17 + MINUTES

Device Name Manufacturer	Recording Time (Minutes)	[illegible]	Model	[illegible]
AlphaTalker Prentke Romich Company	37	4	AT-1	$2645
Digivox DynaVox Systems, Inc.	142	48	Digivox2-142	$3250
Dynamo DynaVox Systems, Inc.	30	Dynamic Display	DMO	$1795
Macaw 3+ Zygo Industries	19	32	Macaw3+	$2645

Because digitized speech AAC devices have a fixed amount of recording time, the number of messages and the length of messages sometimes become competing factors. While some devices have pre-assigned maximum message lengths, most devices allow for a range of individual messages of varying lengths within the total recording time available. Some also offer limited language storage and retrieval features, such as iconic encoding and levels. These are described in subsection B. Although all AAC devices with digitized speech produce a finite number of pre-recorded messages (or message units), these messages can be changed to accommodate an individual's varying communication needs by simply recording new messages to replace those no longer needed.

2. Synthesized Speech AAC Devices

Synthesized speech output AAC devices incorporate two categories of AAC devices (Category #2 and Category #3). Synthesized speech AAC devices use a technology that translates the user's input into machine-generated speech using algorithms representing linguistic rules, including rules for pronunciation, pronunciation exceptions, voice inflections, and accents of the language. The user is not restricted to messages that are pre-stored by someone else, as occurs with digitized speech AAC devices; rather the user creates a message using letters, words, or symbols. The AAC device then 'translates' the input into speech. Research examining the intelligibility of the synthesized speech output in AAC devices has found that modern speech synthesizers, such as DECTalk™ designed by the Digital Equipment Corporation, which is recognized as the industry standard, have word and sentence intelligibility of over 95% when compared to natural speech and are preferred over impaired speech by both unfamiliar and familar communication partners. (Rupprecht, Beukelman & Vrtiska, 1995).

Synthesized speech AAC devices are 'open' systems because users independently can construct original messages. This is often referred to as generative speech capability. Individuals who need devices with synthesized speech possess the cognitive and linguistic capacity to formulate messages independently. These individuals typically have primary physical impairments with dysarthria or apraxia secondary to ALS, cerebral palsy, multiple sclerosis, Parkinson's disease, brain stem stroke, and those persons with traumatic brain injury who have relatively preserved linguistic and cognitive skills. In addition, individuals with mild language difficulties, including some with mild aphasia, can utilize synthesized speech devices to generate words and sentences independently or to use pictographic symbols to generate language.

As further described below and in Section 3, synthesized speech AAC devices are distinguished by two unique features: (1) the method by which the user generates messages and (2) the method by which the user accesses the device. When considering a synthesized speech AAC device, the treatment goal is to identify the device that allows the individual with a severe communication impairment to communicate as efficiently as possible across environments. Therefore, the assessment process must match a user's linguistic skills to the message formulation, storage, and retrieval features available in a particular AAC device. The assessment process also must identify the most appropriate user interface, *i.e.*, a way to access the device to produce messages.

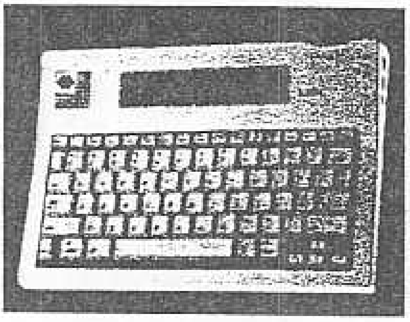
a. Category #2: AAC Devices With Synthesized Speech Output, Which Require Message Formulation By Spelling And Device Access By Physical Contact Direct Selection Techniques

Category #2 devices require spelling (which includes using a limited number of alphanumeric codes) for message formulation and access by physical contact direct selection techniques. Clinical indicators for this category require that the individual have sufficient spelling skills to generate messages independently and be able to access the device using a physical contact direct selection technique (pointing with finger, head stick, mouth stick, etc.). Finally, based on the communicative needs assessment, persons requiring Category #2 devices do not need to construct, store, and retrieve lengthy messages. Defining features of this category of AAC devices are described below.

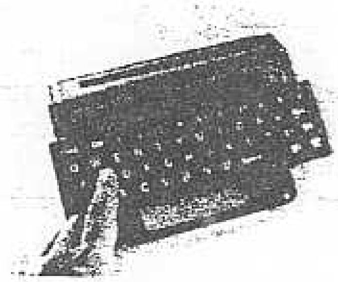
i. Message Generation: Spelling

The most straightforward way to formulate a message is for the non-speaking individual to spell letter-by-letter using an AAC device with an alphanumeric keyboard. An important clinical indicator is that the person be able to spell sufficiently well to generate messages. Synthesized speech devices in this category are technologically unique in the method of message generation, *i.e.*, spelling. Examples include the Link and the LightWriter [model # 25/35] as illustrated in FIGURE 3.

Figure 3: AAC Devices With Synthesized Speech Output, Which Require Message Formulation By Spelling And Device Access By Physical Contact Direct Selection Techniques



Link



Light Writer SL 25/35

Depending on the ability of the user, the process of generating messages using spelling can be laborious. For this reason, some spelling-based AAC devices offer a limited selection of rate enhancement strategies such as alphanumeric encoding. This feature is discussed in section II.

ii. Access method: Direct selection

Operating an AAC device by direct selection requires that an individual make physical contact with the selection set (letters, symbols, codes) of the device to construct a message. The individual can make physical contact using a body part (*e.g.*, fingers, toe) or by using an adaptive peripheral device (*e.g.*, a splint, mouth stick, head pointer, head mouse). The standard computer keyboard is an example of a device that uses direct selection (by the fingers) as an operating technique. The keyboard, display, or touch screen of AAC devices are similar to computer keyboards but typically are more adaptable. To accommodate persons with a range of physical and/or visual impairments many AAC devices permit the 'keys' or 'cells' to be configured in different sizes; permit variable amounts of pressure or time required to activate keys or cells; and enable key repeat features to be turned off.

AAC devices in all other categories allow for multiple access methods, *i.e.*, both direct and indirect selection methods. Only this category of AAC devices limits the operating method to physical contact direct selection. Examples of AAC devices are listed below in Table 12.

TABLE 12: AAC DEVICES WITH SYNTHESIZED SPEECH OUTPUT, WHICH REQUIRE MESSAGE FORMULATION BY SPELLING AND DEVICE ACCESS BY PHYSICAL CONTACT DIRECT SELECTION TECHNIQUES

DEVICE NAME/ MODEL	RATE ENHANCEMENT/ MESSAGE STORAGE (YES/MINIMAL/NO)	DIRECT SELECTION OPTIONS (KEYBOARD/TOUCH)	PRICE (RETAIL)
LINK	Y	Keyboard	$1,395
LightWriter SL25LQBDO SL25LQFDO SL25LQF/BDO	Y	Keyboard	$3,095 $3,345 $3,595
LightWriter SL35LQBDO SL35LQFDO SL35LQF/BDO	Y	Keyboard	$4,070 $4,425 $4,780
LightWriter SL35C SL35 Big Keys	Y	Keyboard	$5,585 $5,795

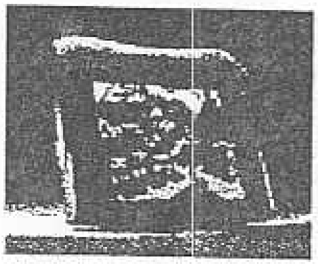
b. Category #3: AAC Devices With Synthesized Speech Output, Which Permit Multiple Methods Of Message Formulation And Multiple Methods Of Device Access.

The devices in this category provide expanded options for constructing, storing, and retrieving messages, and they offer multiple methods for accessing an AAC device. An important clinical indicator for this category is that an individual be able to generate language independently and efficiently using text, words, and/or pictographic symbols. Other indicators include the individual's need for extensive strategies for message construction, message storage, and message retrieval, and the need for individual's indirect methods of access. The message generation and access features in this category are discussed in more detail below.

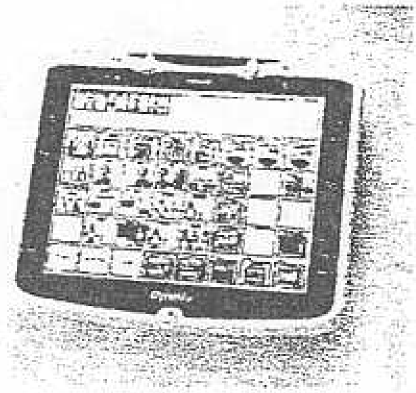
i. Message generation: Multiple methods

This category of AAC devices represents language using text and/or pictographs. Thus, a non-literate user with the cognitive and linguistic abilities to generate messages independently can use familiar pictures or icons (or ones they can learn) to communicate their thoughts, opinions, and needs. For example, an individual may store the message 'Please call my wife' and select it later by pointing first to the cell with the printed word 'phone,' and then to the cell with a picture of his spouse. Synthesized speech AAC devices with multiple message generation methods also enable users to store many messages and retrieve them efficiently using a variety of rate enhancement techniques. FIGURE 4 below illustrates two AAC devices in this category, the Freestyle and DynaVox, both of which offer touch screens which the user can operate by pressing an item or box on the screen to construct a message.

FIGURE 4: AAC DEVICES WITH SYNTHESIZED SPEECH OUTPUT, WHICH PERMIT MULTIPLE METHODS OF MESSAGE FORMULATION AND MULTIPLE METHODS OF DEVICE ACCESS



FREESTYLE
Assistive Technology, Inc



DYNAVOX 3100
DynaVox Systems, Inc.

During the AAC assessment process, the SLP determines whether the individual possesses the linguistic capacity to formulate messages independently. If so, the SLP seeks to establish whether the person needs a device that can store a large number of messages, and can store lengthy messages and retrieve them efficiently. In such cases, the individual must be able to rely primarily on icons or pictographs to produce their messages as well as spelling to generate specific words or messages for which there are no appropriate icons or pictographs. This category of AAC devices is unique and often is required by individuals with primary physical impairments (dysarthria), as well as by some individuals with moderate aphasia and apraxia. The devices in this category are identified in TABLE 13.

TABLE 13: AAC DEVICES WITH SYNTHESIZED SPEECH OUTPUT, WHICH PERMIT MULTIPLE METHODS OF MESSAGE FORMULATION AND MULTIPLE METHODS OF DEVICE ACCESS

DEVICE NAME MANUFACTURER	[illegible]	MODEL #	PRICE (RETAIL)
Axis 1600/Vanguard Prentke Romich Company	Dynamic	AXS-VGW	$6,995
Axis 1600/Scan/WiVox Prentke Romich Company	Dynamic	AXS-WSV	$5,995
Dynamyte 3100 DynaVox Systems, Inc.	Dynamic	DMYT3100	$5,995
Dynavox 3100 DynaVox Systems, Inc.	Dynamic	DNV3100	$6,495
Freedom 2000 Words+, Inc.	Dynamic	Freedom 2000	$5,995
Freestyle Assistive Technology, Inc.	Dynamic	FS 32/1.1	$6,615
Liberator Prentke Romich Company	Static	LIB2KEY	$8,945
Optimist 100 Zygo Industries	Dynamic	Optimist 100	$4,995

Optimist 160 Zygo Industries	Dynamic	Optimist 160	$5,995
Pegasus Lite Words+, Inc.	Dynamic	Pegasus Lite	$6,995
Synergy mAAC 2 Synergy	Dynamic	Synergy mAAC 2	$8,675
Vanguard Prentke Romich Company	Dynamic	VG-NON	$7,995

ii. Access (user interface): Multiple methods

Another defining feature of Category #3 relates to the ways in which an individual can access/operate an AAC device. There are two options: direct and indirect selection.

Direct selection. User interfaces that require physical-contact direct selection are discussed above in subsection a. Other direct selection options involve the use of electronic accessories that enable individuals to point to a display using a head mouse, optical head pointer, light pointer, infrared pointer or joystick. These are discussed below in Section III.

Indirect selection. AAC devices that support indirect selection have special software and hardware that allow them to interpret input from a source other than the physical keyboard. The most common indirect selection technique is scanning. With this access method, elements of the selection set of the AAC device (letters, icons, etc.) are systematically presented visually and/or auditorily to the user. The user selects the message by activating a switch at the moment the cursor or indicator electronically highlights the desired word, letter or icon. Linear, row-column, and directed scanning techniques are examples of available scanning techniques. Some devices can be accessed using Morse code. In Morse code, the individual uses one or two switches to send a combination of 'dits' and 'dahs' that represent the letters of the alphabet, numbers, and punctuation. Individuals whose severe physical impairments prevent them from using direct selection techniques are evaluated to determine if they can use scanning and/or Morse Code. These methods require only a minute movement (eye blink) for successful operation of the appropriate AAC device.

Both scanning and Morse code techniques require the use of 'switch technologies.' The types of switches are discussed in Section III. Indirect methods of access to AAC devices are insufficient motor control to access messages directly, and the ability to activate switches reliably for scanning or to generate messages using Morse code. These indirect access approaches are designed to meet the broad range of communication needs, coupled with the cognitive, linguistic, sensory, and motor abilities of the user.

II. KEY AAC DEVICE CHARACTERISTICS

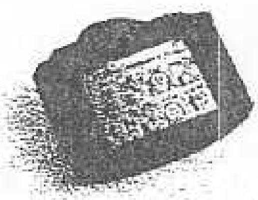
A. Methods Of Displaying Language

Currently, AAC devices use two distinct methods of displaying language/message components (letters, words, icons, pictures): dynamic displays and static displays.

1. Dynamic Displays

A dynamic display depicts language in an electronic format. As a result, the information displayed is 'changeable' by the user. That is, when the user selects a location on the display, the device either speaks a message immediately or changes what appears on the screen. FIGURE 5 illustrates an AAC device with dynamic display and AAC software. In addition to displaying language, dynamic displays are designed to facilitate the effective and efficient retrieval of language. Messages typically are organized by topic into 'electronic pages,' which become familiar to the user. These may include, among others, context-based pages (home, physician's office), taxonomic-based pages (family, foods, medicines), conversational pages (greetings, partings), and alphanumeric pages (alphabet). Individuals learn to compose messages by navigating through the pages electronically. This dynamic display allows the user to see only the message components that are most relevant at the time and to switch easily between display screens. Some devices with dynamic displays have onscreen keyboards so that literate users can spell words when necessary.

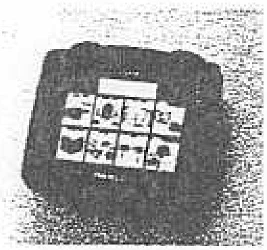
FIGURE 5: AAC DEVICES WITH DYNAMIC DISPLAYS



DYNAMO

DynaVox Systems, Inc

(digitized speech output)



DYNAMYTE 3100

DynaVox Systems, Inc

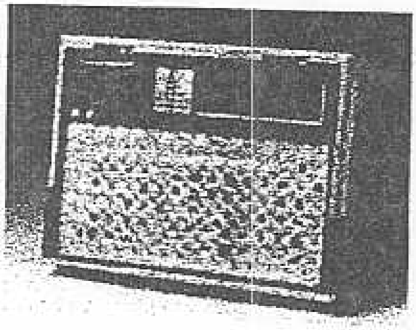
(synthesized speech output)

Dynamic display AAC devices are available for users who require 'open' systems (devices that use synthesized speech) as well as for users who require a 'closed' system (devices that use digitized speech). Dynamic display devices are clinically indicated for individuals who need to access multiple levels of vocabulary independently to generate messages. Dynamic displays also are appropriate for individuals who have difficulty learning and remembering a large number of codes. Because dynamic displays essentially are computer screens, devices with dynamic displays typically offer a range of rate enhancement features and message storage options. They are available among devices in Categories # 1 and # 3 and the AAC software accessories category.

2. Static Displays

A static display provides language symbols in a tangible format. An example of a static display is a computer keyboard, which has a fixed layout of letters, numbers, punctuation marks and operational command keys. Most digitized speech AAC devices have static displays, which typically are constructed by an SLP. FIGURE 6 illustrates a digitized speech device with a static display.

FIGURE 6: AAC DIGITIZED DEVICES WITH STATIC DISPLAYS



This Minspeak device enables a user to access a large vocabulary using iconic sequences

LIBERATOR
Prentke Romich
(Synthesized Speech)

The user selects a picture and the device speaks the stored message.

MESSAGEMATE
Words+, Inc.
(Digitized Speech)

Static displays often are used for individuals who have limited vocabulary needs, especially those able either to change displays independently or to have others who are readily available do so. At the same time, displays that are 'static' do not necessarily generate a limited amount of language. For example, a static display containing the letters of the alphabet can produce any message. Likewise, by using encoding techniques, a large number of messages. Devices that use a Minspeak approach are good examples of static display devices that generate many messages.

B. METHODS OF STORING AND RETRIEVING LANGUAGE

The goal of all AAC devices is to allow individuals to meet the communication needs arising in the course of their daily activities. Therefore, a major design consideration in AAC devices is the need to provide access to more language/messages than can fit within the physical dimensions of a given display. This characteristic is called 'language storage and retrieval.' AAC devices use two methods to store/retrieve language: levels and message encoding techniques. These features can be found in AAC devices in Categories #1 and #3, and to a lesser degree, among the AAC devices in Category #2.

1. **Levels**

Many devices (both digitized and synthesized) use a 'level' approach to language storage and retrieval. 'Level' capability means that each cell shown on the display can produce more than one message. Multiple levels permit the storage of more symbols, letters, words, or other messages than can fit within the physical dimensions of an AAC device display. By offering a 'level' alternative, AAC device users have access to more of the language they require to meet their communication needs.

A user with many levels who needs access to a large vocabulary must recall where a desired message is located or stored. Because this may be very difficult for the individual, AAC devices offer different strategies to aid users in retrieving messages efficiently. Dynamic display devices allow vocabulary to be organized in ways meaningful to the user and take advantage of an individual's 'recognition memory.' Devices with static display devices that use a level strategy require multiple overlays. Of course, persons who are physically unable to change the overlay by themselves because of upper extremity involvement will be dependent upon others to do so.

2. Message Encoding

Some devices offer the use of numeric, letter or iconic codes as a way to store and retrieve messages, and as described below, as a rate enhancement technique. 'Coding' capability means that users, by selecting the cells of a display in sequence, can generate a large number of stored messages from just a few 'hits.' Some form of coding is available across all AAC device categories. An important clinical indicator for language encoding is the user's ability to learn (and recall) the codes. Types of coding used in AAC devices include the sequencing of numbers, letters (abbreviation expansion, instant messages), words/icons (semantic encoding/Minspeak) and Morse code (dits and dahs). Clinical indicators for encoding are determined through the AAC assessment process and relate to the type and number of codes to be memorized. An advantage of coding is that with just a few selections, individuals can access longer messages and enhance their rates of communication. A disadvantage is that individuals must memorize codes to use them effectively.

a. Encoding Strategies

As discussed, coding is a way to retrieve messages that have been stored in an AAC device. Coding strategies also can be considered rate enhancement techniques.

- **Numeric codes**: Some devices, as well as some AAC software, enable individuals to use numeric codes (macros) to stand for a word, phrase, or sentence. The user enters one or more numbers, and the device outputs the complete stored vocabulary item. While numeric codes can be memorized, they are often arbitrary. It is difficult for most people to memorize more than 100 numeric codes.

- **Letter codes** (Abbreviation expansion/instant messages). Some devices and AAC software allow a user to enter a shortened form of a word or phrase (an abbreviation) to stand for the entire word or phrase (the expansion). The AAC device automatically expands the abbreviations. People with limited spelling ability as well as competent spellers can enhance their rate of communication by creating words/word combinations in less time. The integration of an abbreviation expansion technique with spelling allows the user to use only the first letter of words or variations of letter combinations (contractions, truncations) in common expressions or proper names in order to represent messages. For example, if the sequence 'ASAP' is selected, the words 'as soon as possible' are printed to the display and/or spoken by the speech synthesizer. This device feature can be critical for individuals with limited motor abilities, powerful vocabulary needs, and good spelling skills.

- **Semantic encoding.** This approach codes words, sentences, and phrases on the basis of their meaning (*i.e.*, MinSpeak). Semantic encoding substitutes pictorial representations (icons) for numerical or letter codes, so the code is easier to remember. The visual feedback from language rich icons (color, shape, content) provides the user with a memory prompt that aids the recall of the sequence that represents vocabulary words or word combinations. This strategy enables a user to communicate a large vocabulary with few keystrokes, thereby increasing the rate of communications. Specific Minspeak programs such as Word Strategy are designed to meet the needs of specific groups of AAC device users. Another feature of some semantic encoding programs is icon prediction, which can increase rate by restricting the selection set to the user thus aiding recall.

C. Methods for Enhancing Rate

While AAC devices provide a way to communicate for people unable to speak, they generate language at a far slower rate than natural speech. Most individuals who use an AAC device want to approximate normal conversational rates but are limited by the technology and such factors as deficits in cognitive/linguistic, motor, and/or sensory skills. Rate enhancement techniques maximize output (produce a sufficient quantity and quality of messages efficiently) while minimizing input (fewer keystrokes or activations). In other words, with rate enhancement options, users can produce more language with fewer keystrokes. Some are available across device categories. The two primary rate enhancement strategies are encoding and prediction. Encoding strategies are discussed above. A description of prediction strategies follows.

1. Message Prediction

Message prediction techniques speed the message generation process by offering predictions to complete words or phrases based on prior user input. This contrasts with encoding strategies, which require the user to memorize and recall multiple code sequences to construct their utterances. The algorithms employed to guide predictions in AAC devices are based on research examining frequency of usage in the target language (English). For example, in a device that has single-word prediction such the LightWriter by Zygo, after the user types 'th' the device predicts 'the' because it is the most frequently used word in the English language beginning with the letters 'th.' Individuals who have sufficient spelling and reading skills to spell the beginning of words and to recognize the desired word from the prediction set often find prediction strategies useful in decreasing message construction time. Another clinical indicator for use of prediction strategies is lack of desire or inability to memorize alphanumeric and/or iconic codes. Because the user simply selects the desired word from the prediction set, no memorization is required. Extensive message prediction-based strategies are available only on synthesized speech based devices in Category #3 and in the AAC software accessory category. AAC devices in Category #2 may offer limited message prediction capability.

2. Letter/Word Prediction

As indicated above, some AAC devices offer a feature that automatically predicts the next letter or word when someone is typing. Devices typically come programmed to offer choices based on frequency of occurrence of letter combinations and words, based on the target language. In addition, some devices can 'learn' the user's word patterns with repeated use, altering the prediction pattern accordingly. Some (*e.g.*, LightWriter) offer a fixed number of predictions following a user selection while others allow the user to adjust the number of predictions (*e.g.*, Dynavox, System 2000 with EZ Keys software). Some word prediction programs use grammatical information to increase their efficiency. For example, if the preceding word is 'two' and the next word is a noun, the program will automatically add a plural marker (s, es) to the end of the predicted words (the grammatical rule of number agreement).

III. ACCESSORIES (DEVICE CUSTOMIZATION COMPONENTS)

People who use AAC techniques and are unable to speak or write through traditional means may need different device components to enable them to use an AAC device to meet daily communicative needs. Device customization components (also referred to as AAC accessories) are technologies that permit custom adaptation of AAC devices and include a variety of switches and pointing devices, mounting systems, carrying cases, power accessories and software.

A. Switches/Keyboard Adaptation and Selection (Pointing) Devices

AAC device accessories that enable people to access AAC devices can be both electronic and nonelectronic. Some are designed to support direct selection; others support indirect access techniques. Table 14 provides examples of AAC Access technologies.

Table 14: Examples of AAC Access Technologies

Nonelectronic All Device Sub Categories	Electronic (Direct) Device Categories 1 & 3	Electronic (Indirect) Device Categories 1 & 3
Hand-held stylus	Light pointers	Pneumatic switch
Pointers (head, foot)	Infrared pointers	Rocking lever switch
Splints	Eye-gaze systems	Tread switch
Keyguards	Joysticks	
Mouth stick	Optical head pointers	
	Head controlled mice	

The selection of switches, keyboard adaptations, and pointing devices is determined by the SLP and, as necessary, an occupational therapist, based on the user's physical capabilities, such as motor skills and visual abilities, and the type of AAC device the individual needs for communication.

B. Mounting Systems

Mounting systems are necessary to place AAC devices, switches and other access peripherals in a stable position relative to the user. Without appropriate mounting for a device and/or switch, individuals with severe motor impairment are unable to use appropriate AAC devices to transmit messages. Good positioning underlies successful access and device use. Depending upon an individual's disabilities and communication needs, mounting systems may be required on a wheelchair, desk, bed or lap tray, or other locations where the individual resides throughout the day.

C. Carrying Cases

Carrying cases are needed for individuals who are ambulatory and need to communicate in a variety of locations. Specially designed carrying cases are available for some devices. Carrying cases also are used to protect a device. For example, nonambulatory individuals who use their devices in multiple contexts need to safely transport the device from one location to another on a regular basis. Carrying cases are designed to accommodate a user's fine motor skills to enable a person with physical disabilities to open and close the case and communicate effectively.

D. Power

Electronic communication devices require a source of power. Individuals cannot be tethered to a wall outlet in order to communicate. AAC devices therefore require batteries, battery chargers, auto adapters, and AC adapters. While batteries and AC adapters always are included with an AAC device, individuals who use their devices most of the day often need to purchase several batteries and chargers to insure they can communicate regularly.

E. AAC Software

Some manufacturers of AAC technology offer AAC software that is sold separately or in conjunction with a multipurpose hardware platform (*e.g.*, Mayer-Johnson: Boardmaker, Speaking Dynamically; Words Plus: Freedom 2000; Zygo: Optimist). One type of AAC software allows caregivers to create new picto-grams reflecting new vocabulary items or messages which can, at a later time, be added to an AAC device display. Other AAC software can be loaded onto a specially adapted computer and enable it to imitate the functions of an AAC device.[34]

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34 Among the adaptations required to be made by an individual include: purchase of a speech synthesizer, such as DEC Talk, which is capable of producing intelligible speech; purchase of special speakers able to transmit speech clearly and across the distances and in the types of settings in which the user will be communicating; purchase of screen and/or keyboard adaptations required to permit use of electronic direct selection accessories or indirect selection techniques (*e.g.*, a light or touch screen); and purchase multiple batteries for the computer and necessary adaptations, sufficient to enable the individual to communicate throughout the day. In addition, if

Continued on following page

Continued from previous page

these adaptations are made to a laptop computer, consideration must be given to the fact that most laptop computers have plastic cases and screens that are not designed for the rough handling that may be anticipated with use as an AAC device. Another consideration is the need to attach these additional components to the computer: how it will be accomplished, and what will the impacts be on the weight/portability of the resulting system.

By contrast, these additional purchases, as well as the assembly, durability and portability considerations are not presented for any of the AAC devices in sub-categories # 1-3 described in Section 5. For these reasons, AAC software , alone, will be determined by the SLP assessment to be medically appropriate only for a small subset of individuals who require AAC interventions.

SECTION 6: 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, apraxia of speech, or aphasia, 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 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 xxx1 is covered if the patient meets:

a. criteria 1-3 but not

b. criteria 4, 5 and 6

Code E xxx2 is covered if the patient meets:

a. criteria 1-5 and 7 but not

b. criteria 6, 8, and 9

Code E xxx3 is covered if the patient meets:

a. criteria 1-3 and

b. criteria 4 and 6

Clinical Criteria:

1. The individual has a communication disability with a diagnosis of severe dysarthria, apraxia, and/or aphasia.

2. The individual's communication needs that arise in the course of current and projected daily activities cannot be met using natural communication methods.

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

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

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

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

7. 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.

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

9. 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 patient must meet criteria 4 and 6 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 Exxx1.

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IMPACTS OF SEVERE COMMUNICATION DISABILITIES ON INDIVIDUALS

Severe communication impairments can affect every aspect of an individual's life: self-perception, independence, access to health care, and all the other routine activities of daily living that individuals without communication impairments can take for granted. Most importantly, these adverse impacts are as unnecessary as they are severe: because of the existence of AAC interventions, including AAC devices. This Section describes the significant role that AAC interventions, including AAC devices, have within the array of techniques available to treat severe communication disabilities.

AAC interventions are generally recognized as an essential, invaluable, treatment methodology for individuals with severe communication disabilities. This conclusion is based on the half-century long, generally accepted recognition by speech-language pathologists, neuroscience researchers, and the public at large, that the ability to speak and use language is the functional ability that distinguishes human beings from all other species. (*e.g.*, M. Fisher, 1956; M. Batshaw and Y. Perret, 1986; ASHA, 1991; USSAAC, 1991, S. Pinker, 1994; D. Bickerton, 1995; J. Light, 1997; J. Wilford, 1998).[1] The federal Courts also recognize the fundamental importance of the ability to communicate, uniformly holding that state Medicaid programs must cover and provide AAC devices, because the ability to speak is "vital," and that the loss of the ability to speak is the most devastating aspect of any disability. (*Fred C. v. Texas Health & Human Services Commission*, 1996, 1997; *Hunter v. Chiles*, 1996).

The latter conclusion adopted by the Courts is based on the statements of Ruth Sienkiewicz-Mercer. Ms. Sienkiewicz-Mercer is an adult with cerebral palsy and severe dysarthria, who was one of the first individuals provided access to an electronic AAC device. That device was made available to her in 1971, by Howard Shane, Ph.D., one of the speech-language pathologists who contributed to the preparation of this Formal Request. Ms. Sienkiewicz-Mercer has stated:

> Without a doubt, my inability to speak has been the single most devastating aspect of my handicap. If I were granted one wish and one wish only, I would not hesitate for an instant to request that I be able to talk, if only for one day, or even one hour.

(R. Sienkiewicz-Mercer and S. Kaplan, 1989).

Other individuals who have been provided access to AAC devices describe their ability to communicate as a way to retain their human-ness. Rick Creech, an adult with cerebral palsy, has stated:

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1 The formal policy of the American Speech-Language-Hearing Association (ASHA, 1991) and one of the by-laws of the United States Society for Augmentative and Alternative Communication (USSAAC, 1991), each state: "Communication is the essence of human life."

> [When a person who is unable to communicate is among other people,] people [will be] talking behind, beside, around, over, under through and even for you. But never with you. You are ignored until you feel like a piece of furniture.

(Musselwhite and St. Louis, 1988).

Doreen Joseph, who lost her speech following an accident, expresses a similar thought:

> Speech is the most important thing we have. It makes us a person and not a thing. No one should ever have to be a "thing."

(Joseph, 1986).

Jean Dominique-Bauby, the former editor of the fashion magazine *Elle*, who lost his ability to speak and developed locked-in syndrome following a severe stroke, wrote with the aid of a crude eye-gaze device:

> "On June 8, it will be six months since my new life began." . . . Those were the first words of the first mailing of my monthly letter . . . [T]hat first bulletin caused a mild stir and repaired some of the damage caused by rumor. . . . The gossipers [in Paris had] left no doubt that henceforth I belonged on a vegetable stall and not to the human race. . . . [In response,] I would have to rely on myself if I wanted to prove that my IQ was still higher than a turnip's.

(Bauby, 1997).

Beukelman and Mirenda, in their treatise on AAC, wrote: "clearly, someone who has not 'been there' cannot understand the experience of having a severe communication disorder." (D. Beukelman and P. Mirenda, 1998). An earlier article explained why this statement is true:

> For the normal adult who has spoken without difficulty since early childhood, the prospect of being unable to communicate through natural speech is incomprehensible. Efficient communication with colleagues, family, and friends is taken for granted.

(D. Beukelman and K. Garrett, 1988).

Historically, the life experiences of individuals with severe communication disabilities -- who lack the ability to use this distinctly human ability -- were characterized by extraordinary hardships. Indeed, the existence of these endemic adverse impacts have driven the development of AAC interventions, from their emergence as a speech-language pathology discipline in the late 1950's and early 1960's, to the leading edge of research, today. AAC interventions were first invented and implemented because pioneering speech-language pathologists and rehabilitation engineers refused to believe that 'nothing could be done' for people with severe communication disabilities and severe physical disabilities who were unable to benefit from traditional forms of treatment. (Zangari, Lloyd & Vicker, 1994). That same force is driving leading-edge AAC research teams. Among the research now being conducted are experiments with neuro-trophic implants that will enable individuals with severe ALS or other similar conditions to communicate by creating a direct link between the individual's brain and a computer-based AAC device. (*NeuroReport*, 1998, S. Robinson, 1999).

One person who faced risks of extraordinary hardships is Stephen Hawking, the world-renowned physicist who has ALS, and who is perhaps the world's best known AAC device user. (J.Wilford, 1998). In mid-1985, Dr. Hawking was a physicist well known only to a small community of scientists. After he lost the ability to speak due to a tracheotomy, he was extraordinarily restricted in his ability to communicate. As he later explained it, through the use of an AAC device:

> For a time, the only way I could communicate was to spell out words letter by letter, by raising my eyebrows when someone pointed to the right letter on a spelling card. It is pretty difficult to carry on a conversation like that, let alone write a scientific paper.

(S. Hawking, 1995). In late 1985, however, Dr. Hawking was provided with a synthesized speech, computer-based AAC device. A biographer described the impact of the AAC device as follows:

> [The AAC device] completely transformed his life. [Hawking] could now communicate better than he could before the [tracheotomy] operation, and he no longer needed the help of an interpreter when lecturing or simply conversing with people.

(M. White & J. Gribben, 1992). With this AAC device, Dr. Hawking was able to complete *A Brief History of Time* (1988), which catapulted him to international fame.

The experiences of other individuals with severe communication disabilities, who, in the absence of AAC devices, were unable to control even the most mundane aspects of life, and who risked, or who actually experienced extraordinary harm and hardships reinforce the urgency and the importance of AAC interventions. For example, Dr. James Hall, a renowned psychiatrist, faced life-threatening circumstances immediately after developing locked-in-syndrome following a severe stroke. Initially, he was able to communicate only by blinking his eyes. Shortly after his stroke, he was asked whether, due to his condition, he wanted medical treatment to continue. The question however, was phrased incorrectly: one blink for "yes," two for "no." An involuntary twitch, causing a second blink, almost cost Dr. Hall his life. Fortunately, the questioner recognized his error and asked the question again, reversing the meaning of the responses. Dr. Hall, who now uses an AAC device, has returned to the practice of medicine. (D. Wedemeyer, 1996)

A far more typical impact of severe communication disability is the creation of a secondary impairment, aptly called a "cloak of incompetence," and described as the "heaviest burden Americans with significant speech disabilities have always faced." (UCPA, 1992).

> Americans with significant speech disabilities routinely experience isolation, discrimination, illiteracy, institutionalization, unemployment, poverty and despair. Due to the lack of

> understandable speech, these individuals are perceived to be unable to direct their own lives; a perception that often leads to an erosion or outright deprivation of their most basic civil rights and liberties.

(UCPA, 1992).

Extraordinary adverse impacts of this "cloak of incompetence" were felt by Ruth Sienkiewicz-Mercer, who has cerebral palsy, and Julia Tavalaro, who had a severe stroke as a young adult. Each had years of their lives stolen while they were unnecessarily warehoused in public institutions, and where they experienced sustained abuse and neglect. In Ms. Tavalaro's case, caregivers believed she was brain dead and for six years she remained in the back ward of a public institution where she had no input into any aspect of her life. She finally was approached as an intelligent person and examined by Arlene Kraat, a speech-language pathologist who was the President of the International Society for Augmentative and Alternative Communication in 1991-1992, and who has volunteered to be an advisor on Medicare AAC claims. (*See* Appendix I at Tab C). Ms. Tavalaro later described her reaction to her first encounter with Ms. Kraat:

> This is no dream: I'm actually being spoken *to*. . . . For the first time in six years, I feel whole. . . . I raise my eyes for *yes*, hardly able to believe that someone is asking permission before she does something to me.

(J. Tavalaro and R. Tayson, 1997). Ms. Tavalaro, who now uses an AAC device, has become an accomplished poet and published author. (D. Martin, 1991; E. Sandberg-Diment, 1992; J. Tavalaro and R. Tayson, 1997). With an AAC device, Ms. Sienkiewicz-Mercer also has become a published author, has married, and was the leading advocate for the successful closure of the institution where she was forced to remain for 16 years. (Sienkiewicz-Mercer and Kaplan, 1989).

For many other individuals with severe communication disabilities, the adverse impacts of their inability to communicate have ranged from the inability to obtain medical care and unnecessary delays in access to care, to severe physical injuries. For example, one Ohio physician described his difficulty obtaining information from his patient as follows:

> Current inability to communicate has greatly limited his access to medical care and indeed has reduced it to approximately veterinary proportions.

(Ohio Dept. of Human Services, 1988).

In April 1967, an attendant accidentally injured Ruth Sienkiewicz-Mercer. For hours she was untreated because the staff at the public institution did not understand that she was in pain. She was eventually treated for a broken leg, but she was unable to communicate to her doctors and nurses that she felt pain in her hip as well:

> I tried to tell the doctors and nurses about it, but I couldn't communicate with them. Nobody told them about my facial signals. The nurses didn't know if I was deaf, dumb, or what. The nicer ones spoke to me slowly and loudly, as if this would make it

> easier for me to understand them. I wanted to tell them that English was my native language and I understood them very well. but I couldn't get that message across. The nurses kept telling each other "I guess that she doesn't understand us" while I was flashing my yes expression so hard that my face hurt.

Medical professionals did not discover Ms. Sienkiewicz-Mercer's hip problem until October *1969*, more than two years later. (Saideman, 1989).

For Andrew Szczygiel, a Central New York youth with cerebral palsy, the consequences of the inability to communicate was outrageous, yet wholly unnecessary injury. As reported by his speech-language pathologist:

> Andrew has a burn scar on his hand, which occurred because he couldn't tell his attendants at school that they had pushed him up against a radiator and locked his wheelchair wheels in a position where his hand was trapped to sear until the flesh melted off.

(J. Frumkin, 1995).

These may be some of the worst case scenarios of the harm that can arise from the lack of an ability to communicate, but the adverse impacts of a severe communication disability go far beyond these discrete examples. All too common are reports of broken bones that were not discovered for days (*In re: Keith C.*, 1991); infections that were not identified and treated until they had become extremely severe (*In re: Anonymous*, 1988); and sources of pain that were not localized and timely addressed (*In re: Shannon*, 1990). Indeed, for some individuals, the frustrations associated with the inability to communicate may rise to the level of a mental health impairment, which requires treatment. (Crawford, 1987).

These adverse impacts still do not provide a complete picture. The broadest perspective of life with a severe communication impairment is best illustrated by examining the growing body of first-hand accounts by individuals who use AAC devices.

The perspective of these individuals is perhaps best captured by the following statement by a young attorney who was unable to speak due to ALS:

> When I first realized that I would be unable to speak someday, I viewed it as losing my life. Communication was my life. Now, I realize that was a little overly dramatic, but not much. *Speechlessness is not a loss of life, but a loss of access to life . . .*

(D. Beukelman and K. Garrett, 1988). For this man, the access to life he lost was to his friends, both to their friendly conversations and intellectual debates. By use of an AAC device, however, that access was restored.

For Celia Cooper, who was a homemaker, and who developed anarthria due to ALS, the loss of access to life was the ability to interact with her husband of 55 years and with her siblings, children and grandchildren, to take care of her personal needs and health care, to maintain her home and maintain social contacts. The loss of speech was profoundly disrupting to her role and responsibilities in her family and profoundly isolating, both to her and to her husband. Indeed, Mrs. Cooper's anarthria precluded the very speech -- about home, family, health and social matters -- that researchers have established is typical of the conversations of older women. (Stuart, Vanderhoof & Beukelman, 1993). Mrs. Cooper subsequently was able to restore some of these functional abilities when she obtained an AAC device.

Similarly, Emyln Jones, an adult who had a stroke, described -- through use of his synthesized speech computer-based AAC device -- the extent to which the AAC device enabled him to regain "access to life." He reported that he had regained 95 percent of his pre-stroke vocabulary, and that his AAC device

> had opened up his life to express himself, and that he had regained up to 95 percent of his pre-stroke vocabulary . . . . My [AAC device] has opened up my life again by allowing me to express my thoughts coherently to myself and others. . . . Although the typing process is slow and laborious for me, the joy of expression and communication is unsurpassed.

Mr. Jones was the first Medicare beneficiary known to have had an AAC device claim approved by a Medicare Administrative Law Judge. In his decision approving the claim, the ALJ observed:

> His introduction to the [AAC device] and subsequent learning of the device has resurrected to a great measure his ability to communicate and become much more functional to the extent that he can maintain greater independent living. . . . There is no question, given the evidence, that the [AAC device] has restored and improved his life . . . Without this device, as the evidence points out, the claimant's life would continue to be severely restricted and his ability to enjoy the fruits of life would not be available.

(*In re: Emyln J.*, 1993).

Jean Dominique-Bauby, who never had access to an electronic, voice-output AAC device, but who instead relied on a very taxing, manual, eye-gaze system, provides -- in this context -- an even more powerful statement about the importance of access to an AAC intervention:

> The identity badge pinned to Sandrine's white tunic says "Speech Therapist," but it should read "Guardian Angel." She is the one who set up the communication code without which I would be cut off from the world.

(Bauby, 1997).

In conclusion, the first principle in the Hippocratic oath is to "prescribe regimen for the good of my patients according to my ability and my judgment." It is on this basis that physicians and allied health professionals, including speech-language pathologists, occupational therapists, and rehabilitation engineers, have worked together for almost four decades, to develop and implement AAC devices and interventions.

At present, the Medicare guidance related to AAC Devices does not recognize either the treatment role, or the value of the benefits provided by AAC devices, as described in this Section and throughout both the professional literature and the expanding body of literature created by AAC device users. Instead, that guidance describes AAC Devices as "convenience items." However, based on the foregoing, it is clear that the ability to communicate is not a matter of convenience to individuals with severe communication disabilities, to the professionals who provide -- or who try to provide -- treatment to these individuals, or to anyone else. Indeed, Medicare's own coverage criteria contradict the conclusion that the ability to communicate, even with the aid of a speech-related device, is a convenience. Medicare's coverage of speech language pathology services, of laryngoplasty surgical procedures, and of the artificial larynx, Ultra Voice, and tracheostomy speaking valves, demonstrate that the ability to communicate, even with the aid of a speech-device, is reasonable and necessary medical care, and appropriate for Medicare reimbursement.

Medicare's speech-language pathology services guidance appropriately describes the purpose of all of these services as enabling individuals to achieve "optimum communication independence," based on functional goals that will "have a positive effect on the quality of the patient's everyday functions." (MIM, § 3905.3(A); MHM, § 446(a)(1)(A)). These goals are no different than those set for an individual with communication impairments so severe that AAC devices are required. As explained in Section 3 of this Formal Request, the differences between providing speech-language pathology treatment intended to improve natural speech and AAC devices is only a matter of treatment methodology, not treatment goal. AAC Devices are a treatment technique that will allow individuals for whom natural speech treatment techniques will not be successful to achieve those same functional goals. Thus, whether to ensure the humanity of individuals with severe disabilities, to protect their access to life, to remove effects of the "cloak of incompetence," to provide timely and effective treatment, or to prevent unnecessary harm, AAC devices and interventions should be recognized by Medicare as an effective and often the only possible form of treatment that will provide meaningful benefit.

Estimating Demand For Medicare Payment Of AAC Devices

A. Introduction

For the past decade, the demand for Medicare payment for AAC devices has been substantially restricted by the AAC Device National Coverage Determination. This guidance creates a strong deterrent to the filing of Medicare claims. It also deters the pursuit of appeals to Medicare Administrative Law Judge hearings, where the national coverage determination no longer has binding effect. Although as many as 47,000 Medicare beneficiaries may need AAC devices, and even though every known administrative law judge review of an AAC device appeal has approved the device, there are only 5 known Medicare ALJ decisions related to AAC devices.

For this reason, any change in demand for Medicare payment for AAC devices will depend completely on the withdrawal and/or replacement of the existing AAC device national coverage determination. Moreover, following such a policy change, there will not be an immediate increase in demand for Medicare payment for AAC devices. Both the pace and timing of the increase in demand will be controlled by the relatively small number of Medicare beneficiaries who need AAC devices and the small cadre of speech-language pathologists (SLPs) who currently provide AAC assessment and treatment services to adults. It is estimated that these factors will combine to limit the growth of AAC device demand from between 100 - 200 claims in the first year after a policy change is enacted to 500 - 1,291 claims per year after five years. Based on this estimate, the cumulative number of Medicare AAC device claims will be between 1,300 - 3,300 over five years.

1. Need and Demand are Distinct Concepts

The concepts of AAC device "need" and AAC device "demand" are distinct concepts. AAC device need is a measure of speech and/or language impairment. The need for AAC intervention arises when, due to expressive communication disability, a person is unable to meet the communication needs arising in the course of his or her daily activities. By contrast, demand for Medicare reimbursement requires consideration of a variety of additional non-medical factors. The most important is the availability of certified SLPs with expertise in AAC treatment approaches who conduct AAC needs assessments. Because AAC device need and demand may differ significantly, this section will present estimates for both factors.

B. Total Medicare AAC Device Need

It is estimated that there are fewer than 47,000 persons in the United States who are Medicare beneficiaries in need of AAC devices. This estimate is derived from demographic studies that measure the prevalence of severe communication disability among different populations of individuals with significant disabilities. Persons with severe communication impairment or disability commonly are defined as being "unable to get their message across using speech" (Bloomberg & Johnson, 1990), "as having a condition other than hearing impairment that prevents them from using speech independently as their primary means of

DCLIB-0196219.01-EBCARC5? December 28, 1999 2:21 PM communication" (Matas, Mathy-Laikko, Beukelman & Legresley, 1985), and/or as "non-speaking" (ASHA, 1981; 1991; DeRuyter & Lafontaine, 1987; Lafontaine & DeRuyter, 1987). Persons needing AAC devices are a sub-set of persons with severe communication impairments. Researchers recognize that clinicians further must assess people with severe communication impairments to identify those with AAC needs. (Bloomberg & Johnson, 1990). While there are precise estimates of the prevalence of severe communication impairment in the general population, there is no precise estimate of the sub-set population needing AAC devices.

In 1990, Bloomberg & Johnson reported on a study that sought to measure the prevalence of persons with severe communication impairments in Victoria, the second most populous state in Australia, which has more than four million residents. The study was based on a questionnaire and interview directed to all the health care facilities that provided services to persons with disabilities in Victoria. In total, 1,250 facilities were identified and contacted, and 85 percent responded. These responses identified 5,034 nonspeaking individuals, which equals 0.12 percent of the general population. This study also reported a rough equivalence in the age distribution of the study population: 46 percent of the persons identified as having severe communication impairments were age 21 or younger; 54 percent were older than 21 years (Bloomberg & Johnson, 1990).

The estimate provided here is based on the comprehensive 1990 Bloomberg & Johnson study, which measures severe communication impairment in the general population. Since the Bloomberg & Johnson study did not quantify the need for AAC devices within that larger population, this estimate is a "not to exceed" calculation of AAC device need among Medicare beneficiaries.

1. Calculation of Estimated Prevalence of AAC Device Need among Current Medicare Beneficiaries

Table 1 on the following page describes the calculation of estimated AAC device need among Medicare beneficiaries. There are an estimated 46,604 Medicare beneficiaries with severe communication impairments. Because persons with AAC needs are a sub-set of a class of persons with severe communication impairment, this total, 46,604, represents the estimated maximum ("not to exceed") number of Medicare beneficiaries who need AAC devices.

TABLE 1: ESTIMATING NUMBER OF MEDICARE BENEFICIARIES WITH SEVERE COMMUNICATION IMPAIRMENT

Estimating Persons with Severe Communication Impairment in the United States

PREVALENCE OF SEVERE COMMUNICATION IMPAIRMENT IN THE GENERAL POPULATION	CURRENT UNITED STATES POPULATION (SOURCE: U.S. CENSUS BUREAU, SEPT. 1999)	ESTIMATED NUMBER OF PERSONS WITH SEVERE COMMUNICATION IMPAIRMENT IN THE UNITED STATES
0.12 percent	approx. 273,500,000	328,200

Estimating the Percent of Medicare Beneficiaries among the United States Population

ESTIMATED NUMBER OF MEDICARE BENEFICIARIES IN THE UNITED STATES (SOURCE: HCFA, JUNE 1999)	CURRENT UNITED STATES POPULATION (SOURCE: U.S. CENSUS BUREAU, SEPT. 1999)	ESTIMATED PERCENTAGE OF MEDICARE BENEFICIARIES AMONG THE UNITED STATES POPULATION
38.8 million	approx. 273,500,000	14.2 percent

Estimating the Number of Medicare Beneficiaries with Severe Communication Impairment

ESTIMATED NUMBER OF PERSONS WITH SEVERE COMMUNICATION IMPAIRMENT IN THE UNITED STATES	ESTIMATED PERCENTAGE OF MEDICARE BENEFICIARIES AMONG THE UNITED STATES POPULATION	ESTIMATED NUMBER OF MEDICARE BENEFICIARIES WITH SEVERE COMMUNICATION IMPAIRMENTS
328,200	14.2 percent	46,604 persons

C. Demand for Medicare Reimbursement for AAC Devices

At present, demand for Medicare reimbursement for AAC devices is severely constrained by the AAC Device National Coverage Determination. Any future change in demand for Medicare reimbursement for AAC devices will depend completely on the withdrawal and replacement of the current national coverage determination. Even after Medicare adopts a new AAC device coverage policy, there will not be an immediate increase in demand. Rather, if the new policy reflects current standards of professional practice, as outlined in Section 3 of this Formal Request, there will be a slow and steady increase in demand over a period of years.

Both the size and timing of any increase in demand is controlled by the relatively small number of Medicare beneficiaries who need AAC devices and the small cadre of SLPs who currently provide AAC assessment and treatment services to adults. The small number of SLPs who provide AAC assessment and treatment services, particularly to adults, is the most significant factor that will prevent an immediate increase in demand for AAC devices, since there is a significant gap in the United States and in other countries between the number of people with severe communication impairments that could benefit from AAC assessment and treatment services and the supply of SLPs and other professionals who can provide those services (NIDRR Consensus Report (1992); Bloomberg & Johnson, 1990; Collier & Blackstein-Adler, 1998). This inequality in services-distribution largely reflects the historically greater availability of payment for AAC assessment and treatment through public school programs and Medicaid. Many SLPs are located in public elementary and secondary schools where they are unable to serve adults. (Simpson, Beukelman & Bird, 1998). In addition, communication needs of adults, particularly those with acquired communication impairments are different from those of children and adolescents with congenital communication impairments (Hirdes, Ellis-Hale, & Pearson-Hirdes, 1993). While these statistics *are* changing (*i.e.*, the number of SLPs who provide AAC assessment and treatment services is steadily increasing), these factors are not susceptible to immediate change and as a result will not contribute to an immediate increase in AAC device demand following a change in Medicare policy.

Another contributing factor that will constrain change in demand for AAC devices is the very strong deterrent effect of the current AAC device national coverage determination. For example, during the past two years, based on the uniform success that has been achieved by those beneficiaries who pursued Administrative Law Judge hearings, SLPs have been encouraged to consider filing Medicare claims for AAC devices. Notwithstanding those efforts, the demand for AAC devices remains almost non-existent. Based on this experience, it is anticipated that a significant effort will be required to educate SLPs about a change in Medicare policy permitting payment for AAC devices. Only a few of the SLPs who provide AAC assessment and treatment services to adults are expected to quickly take advantage of a positive policy change and submit AAC device claims. The majority is expected to wait until they are able to assess the implementation of the new policy by Medicare decision-makers. Taken together, these factors will contribute to a slow, small, steady increase in demand for AAC devices over a period of years.

Attempting to quantify future Medicare AAC device demand necessarily requires a degree of speculation. However, based on the factors discussed above, it is reasonable to estimate that in the first year after Medicare announces a change of its coverage policy, approximately 100 - 200 AAC device claims will be submitted by Medicare beneficiaries. If those beneficiary claims for AAC devices are not denied, it is estimated that AAC device claims will increase by 50% each year for the first five-year period. Table 2 on the following page estimates demand for AAC devices over a five-year period.

Table 2: Estimating Change in Demand for AAC Devices after Withdrawal or Replacement of National Coverage Determination

YEAR	PRIOR YEAR TOTAL NUMBER OF CLAIMS	TOTAL NUMBER OF CLAIMS ASSUMING A 50 % INCREASE IN DEMAND PER YEAR
1	n/a	100 - 200
2	100 - 200	150 - 383
3	150 - 383	225 - 574
4	225 - 574	337 - 861
5	337 - 861	500 - 1291

Based on the foregoing, it is estimated that demand for AAC devices may increase from 100 - 200 in the first year after Medicare coverage policy changes, to 500 - 1291 per year in the fifth year. Over this five-year period, it is estimated that there will be approximately 1,300 - 3,300 AAC device claims.

D. Annual Cost Estimates of Medicare AAC Device Coverage

The total cost to Medicare of a policy change supporting AAC device coverage will be very small due to the exceedingly low number of Medicare beneficiaries who are estimated will file AAC device claims. In addition, this Formal Request seeks to establish four categories of AAC devices each of which would be assigned a unique reimbursement rate. It is anticipated that demand will to be divided among the devices in each category.

E. Summary

There are fewer than 47,000 Medicare beneficiaries with AAC device needs. By withdrawing and replacing the current AAC device national coverage determination with guidance and decision making practices that are consistent with the professional literature related to AAC treatment, the Medicare program will experience a slow, small, and steady increase in AAC device claims by these beneficiaries over a five year period. It is estimated that in the first year approximately 100 - 200 AAC device claims will be filed, and that this annual total will increase to 500 - 1,291 devices per year in the fifth year. Thus, it is estimated that over a five-year period, a cumulative total of approximately 1,300 - 3,300 AAC device claims will be filed. Based on this exceedingly low demand estimate, the cost impact to Medicare of AAC device coverage policy reform will be minimal.