FDA Classifies AAC Devices As Prosthetic Devices

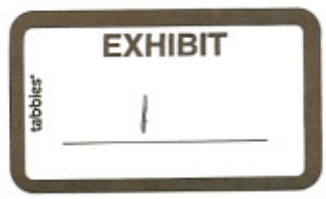
21 C.F.R. Part 890: Physical Medicine Devices

Subpart D: Physical Medicine Prosthetic Devices

890.3710: Powered Communication Systems

(a) *Identification*: A powered communication system is 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.

(b) *Classification*: Class II (performance standards).



of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988; 59 FR 63014, Dec. 7, 1994]

§ 888.5960 Cast removal instrument.

(a) *Identification.* A cast removal instrument is an AC-powered, hand-held device intended to remove a cast from a patient. This generic type of device includes the electric cast cutter and cast vacuum.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[55 FR 48443, Nov. 20, 1990, as amended at 61 FR 1125, Jan. 16, 1996]]

§ 888.5980 Manual cast application and removal instrument.

(a) *Identification.* A manual cast application and removal instrument is a nonpowered hand-held device intended to be used in applying or removing a cast. This generic type of device includes the cast knife, cast spreader, plaster saw, plaster dispenser, and casting stand.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is exempt from the current good manufacturing regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

[52 FR 33702, Sept. 4, 1987, as amended at 53 FR 52954, Dec. 29, 1988]

PART 890—PHYSICAL MEDICINE DEVICES

Subpart A—General Provisions

Sec.

Subpart B—Physical Medicine Diagnostic Devices

Subpart C [Reserved]

Subpart D—Physical Medicine Prosthetic Devices

of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, regarding general requirements concerning records, and § 820.198, regarding complaint files.

[48 FR 53047, Nov. 23, 1983, as amended at 54 FR 25052, June 12, 1989]

§ 890.3710 Powered communication system.

(a) *Identification.* A powered communication system is 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.

(b) *Classification.* Class II (performance standards).

§ 890.3725 Powered environmental control system.

(a) *Identification.* A powered environmental control system is an AC- or battery-powered device intended for medical purposes that is used by a patient to operate an environmental control function. Examples of environmental control functions include the following: to control room temperature, to answer a doorbell or telephone, or to sound an alarm for assistance.

(b) *Classification.* Class II (performance standards).

§ 890.3750 Mechanical table.

(a) *Identification.* A mechanical table is a device intended for medical purposes that has a flat surface that can be inclined or adjusted to various positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[48 FR 53047, Nov. 23, 1983, as amended at 59 FR 63014, Dec. 7, 1994]

§ 890.3760 Powered table.

(a) *Identification.* A powered table is a device intended for medical purposes that is an electrically operated flat surface table that can be adjusted to various positions. It is used by patients with circulatory, neurological, or musculoskeletal conditions to increase tolerance to an upright or standing position.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[48 FR 53047, Nov. 23, 1983, as amended at 61 FR 1125, Jan. 16, 1996]

§ 890.3790 Cane, crutch, and walker tips and pads.

(a) *Identification.* Cane, crutch, and walker tips and pads are rubber (or rubber substitute) device accessories intended for medical purposes that are applied to the ground end of mobility aids to prevent skidding or that are applied to the body contact area of the device for comfort or as an aid in using an ambulatory assist device.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice regulations in part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

§ 890.3800 Motorized three-wheeled vehicle.

(a) *Identification.* A motorized three-wheeled vehicle is a gasoline-fueled or battery-powered device intended for medical purposes that is used for outside transportation by disabled persons.

(b) *Classification.* Class II (performance standards).

§ 890.3825 Mechanical walker.

(a) *Identification.* A mechanical walker is a four-legged device with a metal frame intended for medical purposes to provide moderate weight support while walking. It is used by disabled persons who lack strength, good balance, or endurance.

Medicare Coverage of AAC Devices as Prosthetic Devices

1. Congress established prosthetic devices as a distinct Medicare covered benefit category.

42 U.S.C. § 1395x(n).

2. HCFA has established distinct Medicare regulations defining prosthetic devices.

42 C.F.R. § 410.36; 414.202

3. Medicare "national coverage decisions" for prosthetic devices are distinct from those for durable medical equipment

DME = § 60
Prosthetic devices = § 65

4. No Medicare guidance states that national coverage decisions for one benefit category are to be applied to consideration of items or services under another benefit category.

5. The Medicare national coverage decision for "AAC devices" is found in the durable medical equipment section of listing of coverage decisions; it references only the Medicare Act definition of durable medical equipment; no reference is made to the definition of prosthetic devices, or to any element of the definition of prosthetic devices

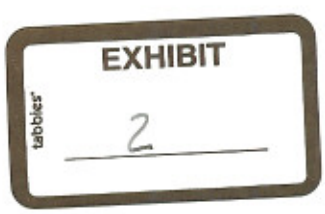
"Augmentative Communication Devices"

Augmentative Communication Device	see Communicator
Communicator	Deny -- convenience item, not primarily medical in nature (§ 1861(n) of the Act).

Medicare National Coverage Decision 60-9, reprinted in CCH Medicare & Medicaid Guide, ¶ 27,221 at p. 29,803 (Oct. 1992)(DME Reference List).

5. There is no national coverage decision for AAC devices under the Medicare prosthetic device benefit category.

In the absence of national coverage guidance directed specifically to the item being sought, the DMERCs are authorized to use their discretion, and to consider coverage decisions for similar items. Medicare Carriers Manual.



6. Within Medicare prosthetic device benefit category, 2 national coverage decisions exist for AAC devices: electronic speech aids (artificial larynx) and tracheostomy speaking valves, and both *support* coverage

"Artificial Larynx" or "Electronic Speech Aids"

The artificial larynx is described by Medicare guidance as an "electronic speech aid:"

Electronic speech aids are covered under Part B as prosthetic devices when the patient has had a laryngectomy or his larynx is permanently inoperative. There are two types of speech aids. One operates by placing a vibrating head against the throat; the other amplifies sound waves through a tube which is inserted into the user's mouth. A patient who has had radical neck surgery and/or extensive radiation to the anterior (front) part of the neck would generally be able to use only the "oral tube" model or one of the more sensitive and more expensive "throat contact" devices.

National Coverage Decision 65-5, Medicare Coverage Issues Manual.

"Tracheostomy Speaking Valves"

A trachea tube has been determined to satisfy the definition of a prosthetic device and the tracheostomy speaking valve is an "add on" to the trachea tube which may be considered a medically necessary accessory that enhances the function of the tube. In other words, it makes the system a better prosthesis. As such a tracheostomy speaking valve is covered as an element of the trachea tube which makes it more effective.

National Coverage Decision 65-16, reprinted in CCH Medicare & Medicaid Guide, ¶ 27, 201, at p. 29,284 (October 1996).

7. AAC devices, such as the Dynavox and Dynamyte meet all the criteria in the Medicare definitions of prosthetic devices, and are comparable in function to the artificial larynx.

Prosthetic devices are devices "which replace all or part of an internal body organ (including colostomy bags and supplies and supplies directly related to colostomy care . . ."

42 C.F.R. § 410.36; 414.202.

Prosthetic devices are devices "which replace all or part of the function of the permanently inoperative or malfunctioning internal body organ."

Medicare Carriers Manual, § 2130.

AAC devices replace the function of impaired portions of the brain, nerve pathways, and/or organs and body structures that control speech. When all of these parts of the body function properly and in precise coordination, intelligible speech is the result. When they do not, intelligible speech is precluded.

The artificial larynx replaces the function of *one* of these body structures: the vocal folds, but is useless if either of the other body parts necessary to produce intelligible speech are impaired. By contrast, an AAC device such as the Dynavox or Dynamyte will be of use when these other body structures are mal- or non-functioning.

8. Other major health-benefits funding programs -- federally administered; state-administered; and privately administered -- all recognize and classify AAC devices as prosthetic devices.

Department of Veterans Affairs
Medicaid
Health Insurance

9. Medicare administrative law judges are not obligated to apply the durable medical equipment national coverage decision for AAC devices. They also have full discretion to consider AAC devices under the prosthetic device benefit. Since 1993, every ALJ who has considered an AAC device has approved its coverage and funding either as a prosthetic device, durable medical equipment, or under both benefits categories.

10. One reason why administrative law judges have not applied the AAC national coverage decision is that HCFA acknowledges it has no records that explain its basis. Another reason is that the conclusion stated in the coverage decision is internally inconsistent with other Medicare guidance: first, "speech" as a functional ability, is not a "convenience" to the Medicare program. Medicare covers and provides speech-language pathology services; AAC intervention has long been recognized as a speech-language pathology treatment methodology and within the scope of practice of speech-language pathologists; the range of functional speech-language pathology goals for which Medicare will provide reimbursement are identical to those for which AAC devices are provided.

Second, speech-related devices are not a "convenience" within the Medicare program, based on its coverage of the artificial larynx and tracheostomy speaking valves

Medicare Guidance Related To AAC Devices

Prosthetic Devices

"Artificial Larynx" or "Electronic Speech Aids"

The artificial larynx is described by Medicare guidance as an "electronic speech aid:"

> Electronic speech aids are covered under Part B as prosthetic devices when the patient has had a laryngectomy or his larynx is permanently inoperative. There are two types of speech aids. One operates by placing a vibrating head against the throat; the other amplifies sound waves through a tube which is inserted into the user's mouth. A patient who has had radical neck surgery and/or extensive radiation to the anterior (front) part of the neck would generally be able to use only the "oral tube" model or one of the more sensitive and more expensive "throat contact" devices.

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Medicare Guidance Related To AAC Devices

Prosthetic Devices

"Tracheostomy Speaking Valves"

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National Coverage Decision 65-16, reprinted in CCH Medicare & Medicaid Guide, ¶ 27, 201, at p. 29,284 (October 1996).

Medicare Guidance Related To AAC Devices

Durable Medical Equipment

"Augmentative Communication Devices"

Augmentative Communication Device	see Communicator
Communicator	Deny -- convenience item, not primarily medical in nature (§ 1861(n) of the Act)

National Coverage Determination 60-9, Medicare Coverage Manual, CCH Medicare & Medicaid Guide, ¶ 27,221 at p. 29,803 (Oct. 1992) (DME Reference List).

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NOTE TO PROCESSING CENTER
FURTHER ACTION NECESSARY

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DEPARTMENT OF
HEALTH AND HUMAN SERVICES
Social Security Administration
OFFICE OF HEARINGS AND APPEALS

DECISION

IN THE CASE OF	CLAIM FOR
Emlyn J[redacted]	Health Insurance Benefits (Medicare Part B)
(Claimant)	
	360-09-1983
(Wage Earner)	(Social Security Number)

This matter is before the undersigned pursuant to a timely Request for Hearing filed by the claimant on August 13, 1992, after an initial denial and denial at a carrier hearing. Following due notice, a hearing was held on June 10, 1993, in Sacramento, California. The claimant appeared but was unable to testify. However, his representative, Mr. Gary Smith, attorney at law, did testify on his behalf.

ISSUES

The issue is whether payment should be made under Part B of Title XVIII of the Social Security Act for the computer and supplies that the beneficiary purchased on December 27, 1990 and January 12, 1991.

The undersigned has determined after carefully considering the documentary evidence of record and the testimony received at the hearing from the claimant's representative, that the claimant's computer and supplies are deemed to be a prosthetic device, but not durable medical equipment. Thus, Medicare is obligated to reimburse the claimant for his computer and supplies.

RATIONALE FOR DECISION

The claimant was in good health until May 5, 1988, when he suffered a severe cerebrovascular accident (stroke) which caused

considerable damage to his brain. He became paralyzed on the right side of his body and resultant damage to his brain caused him to become mute, severely affecting his ability to verbally communicate. While the claimant's ability to think remains unaffected, he is incapable of transmitting his thoughts into long hand or to speak. This condition left the claimant essentially nonfunctional. However, in September 1990, the claimant, with help from a friend, enrolled in a computer class designed for disabled individuals. By learning to use the computer, the claimant has become more functional. As a result, his treating physician, Dr. Stephen H. Foster, wrote a prescription for a computer and computer programs to allow the claimant to communicate (Exhibit 1, p. 7). The claimant ordered his computer and supplies in December 1990, and January 1991 (Exhibit 1, pp. 6, 8). The claimant then requested Medicare reimbursement for his computer and supplies in August 1991 (Exhibit 1, pp. 1-4).

By notice of September 6, 1991, the claimant's request for reimbursement from Medicare was denied (Exhibit 2). An appeal of the denial was filed on his behalf by Ms. Lupita Ochoa, Staff Assistant to Congressman Vic Fazio (Exhibit 3). By notice from Blue Shield of California of October 23, 1991, the claimant was informed that a computer was not a benefit of Medicare and payment was disallowed (Exhibit 4). A request for a carrier hearing was subsequently submitted on the claimant's behalf by Ms. Ochoa on January 14, 1992 (Exhibit 5). By decision of June 19, 1991, the claimant's request for reimbursement of the computer/supplies was denied because it did not meet the Medicare criteria for durable medical equipment. The decision specifically indicated that "durable medical equipment as defined by Medicare is equipment which (1) can withstand repeated use; (2) is primarily and customarily used to serve a medical purpose; (3) is generally not useful in the absence of illness or injury; and (4) is appropriate for use in the home." The decision further indicated that the equipment must be reasonable and necessary for the diagnosis or treatment of an illness or injury (Exhibit 6). As a result of the carrier denial, a request for hearing was filed on the claimant's behalf by Ms. Ochoa on August 12, 1992, contending that his computer assists the claimant in communicating much more easily and clearly (Exhibit 7).

Dr. Foster, by letter of June 3, 1993, indicated the claimant had a marked disability with essentially no use of the right side of his body and had a severe speech problem. The doctor explained that the computer was aiding the claimant in independent living and was of major benefit (Exhibit 11). In a declaration by the claimant of June 10, 1993, he outlined the difficulties that he was encountering in attempting to communicate and conduct his life prior to his acquisition of the computer. He explained how

the computer had opened up his life to express himself and that he had regained up to 95 percent of his pre-stroke vocabulary. He specifically stated, "My computer has opened up my life again by allowing me to express my thoughts coherently to myself and others. Through the computer, my doctors and I estimate that 95 percent of my pre-stroke vocabulary has returned. Although the typing process is slow and laborious for me, the joy of expression and communication is unsurpassed... My computer functions for me like an electronic speech device, or like a Braille keyboard for a blind person. It is prosthetic which replaces the injured part of my body (my brain speech transmission/communication centers)." (Exhibit 12).

His attorney testified at the hearing that the computer is a prosthetic device and that the computer quickly facilitated communication with the claimant as opposed to handwritten notes from the claimant.

In a brief submitted subsequent to the hearing by the claimant's attorney, he argued that the claimant's computer should be considered a prosthetic device. Specifically, he indicated "Part B of Title VIII of the Social Security Act, 42 U.S.C., Section 1395(y)(a)(1)(A), indicates that Medicare reimbursement should be allowed for 'items and services which are reasonable and necessary for the diagnosis or treatment or illness or injury, or to improve the functioning of a malformed body member.' 42 U.S.C. Section 1395x(s)(A) specifically provides coverage for 'prosthetic devices... which replace all or part of an internal body organ.' The Medicare Carriers Manual, at Section 2130, explains that 'prosthetic devices ... which replace all or part of the function of the permanently inoperative or malfunctioning internal body organ are covered when furnished on a physician's order,' as are 'accessories and/or supplies which are used directly' with such a device to 'achieve the therapeutic benefit of the prosthetic or to assure the proper functioning of the device.'" Claimant's counsel went on to indicate that computerized assistive devices are not expressly referenced in the list of examples for prosthetic devices in the Medicare coverage issues manual appendix, but did list "electronic speech aids" as an example of a prosthetic device for a person with an inoperative larynx. He further argued that the computer and supplies which were prescribed for the claimant by his treating physician are intended to replace that malfunctioning internal body organ of the claimant which is the "damaged communications-related portion of Mr. J[redacted]' brain." He then indicated "This 'device' is directly analogous to an electronic speech device, which is eligible for prosthetic coverage because it replaces the functioning of a damaged larynx... Mr. J[redacted]' 'device' helps replace the functioning of his damaged cerebral speech/communication center. Indeed, the assessment from the Assistive Device Center and the Wall Street Journal article in

evidence clearly demonstrate that 'computers help repair damaged brains;' significantly, the Wall Street Journal refers to the Institute for Cognitive Prosthetics, which customizes 'computer-based aids' for brain-injured patients." It was his contention that the Medicare statute itself recognizes coverage provided for items which are designed "to improve the functioning of a malformed body member" which counsel argued was the case with regards to the claimant's computer and computer supplies (Exhibit 13).

Section 1834(h)(4)(B) and (C) regarding payment for prosthetic devices and orthotics and prosthetics indicates:

> "(B) The term 'prosthetic devices' has the meaning given such term in Section 1861(s)(8), except that such term does not include parenteral and internal nutrition, nutrients, supplies and equipment; and
>
> (C) the term 'orthotics and prosthetics' has the meaning given such term in Section 1861(s)(9), but does not include intraocular lenses or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by home health agency under Section 1861(a)(5)."

Section 1861(s)(8) and (9) indicates:

> "(8) prosthetic devices, other than dental (which replace all or part of an internal body organ) including colostomy bags and supplies directly related to colostomy care, including replacement of such devices, and including one pair of conventional eye glasses or contact lenses are furnished subsequent to each cataract surgery with insertion of an intraocular lenses;
>
> (9) leg, arm, back, and neck braces, and artificial legs, arms, and eyes, including replacements if required because of a change in the patient's physical condition;"

The undersigned determines that the arguments by claimant's counsel that the computer/supplies constitutes a prosthetic device are persuasive and credible. The evidence clearly demonstrates that the claimant, now age 70, suffered a severe stroke rendering the right side of his body nonfunctional and significantly damaged the communication/transmission part of his brain to the extent that he is mute. His introduction to the computer and subsequent learning of the device has resurrected to a great measure his ability to communicate and become much more functional to the extent he can maintain greater independent living. It has essentially replaced, as argued by counsel, the malfunctioning part of his body (brain) that caused significant

communication limitations. There is no question, given the evidence, that the computer has restored and improved his life. The claimant's computer and its supplies certainly does meet the criteria that Medicare recognizes to improve the functioning of a malformed body member. The Act does not preclude a computer from being a prosthetic device. In fact, due to the peculiar facts of this case as well as the unusual medical and related facts involved, it clearly satisfies the statutory definition of a prosthetic device as it replaces part of the function of an impaired body organ, Mr. J[redacted]' brain. 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 today's changing and evolving world with regards to computers and how they are applied with regards to disabled people means that the way in which prosthetic devices are viewed and defined is ever evolving. This case is a clear indication of how a computer can replace a damaged brain as a result of a stroke in a way that was not anticipated in the past. As a result, the undersigned determines that reimbursement for the claimant's computer/supplies is warranted.

However, the undersigned affirms the prior determination from Medicare that the computer/supplies does not qualify as durable medical equipment. While the equipment does meet the requirements to withstand repeated use and is appropriate for use in the home and would be useful from a medical standpoint, it cannot be covered because it is also generally useful to individuals in the absence of illness or injury and use of computers in the national economy is for purposes other than medical. Given these facts, it is determined that the assets are not allowable as durable medical equipment.

FINDINGS

After careful consideration of the entire record, the undersigned makes the following findings:

1. The claimant's computer/supplies is deemed to be a prosthetic device.

2. Reimbursement for the computer/equipment that the claimant purchased in December 1990 and January 1991, is warranted.

3. The computer/supplies are not found to be durable medical equipment.

DECISION

It is the decision of the undersigned that Medicare must reimburse the claimant for the purchase of his computer/supplies as a covered prosthetic device. However, it is determined that the computer/supplies are not durable medical equipment.

Nicholas G. Stucky
Administrative Law Judge

August 18, 1993

Date

Health Conditions Associated With AAC Device Needs

Factors Associated with AAC Device Needs:

»» Existence of a severe expressive communication disability; and

»» No other form of speech-language pathology treatment will enable the person to meet his/her daily communication needs using their natural speech or writing.

Health Conditions Associated with AAC Device Needs:

»» Dysarthria

»» Anarthria

»» Dyspraxia

»» Apraxia of Speech

»» Aphasia

MEDICAID PROGRAM COVERAGE OF AAC DEVICES

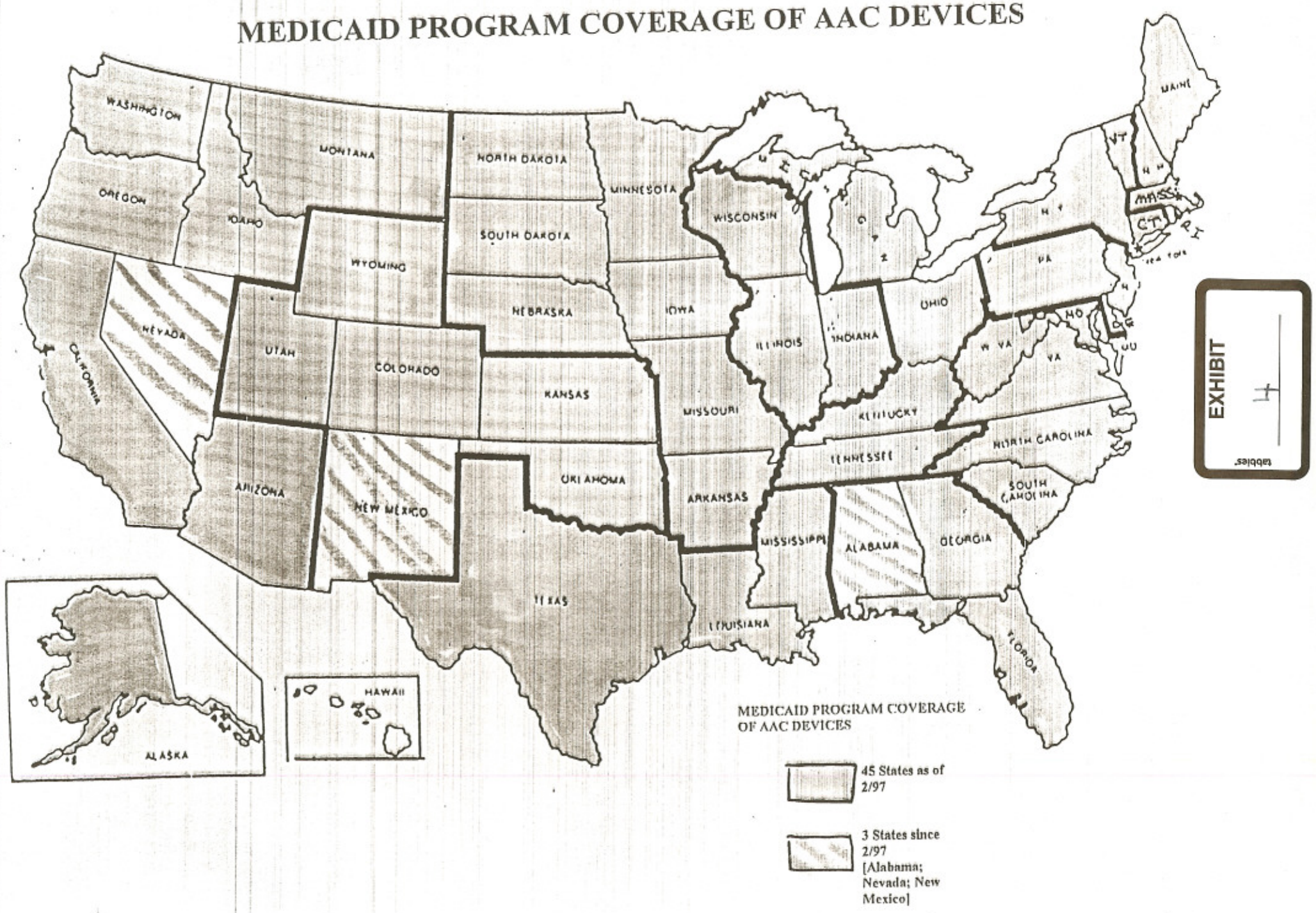

EXHIBIT 4

Speaking Up in Court

Recent federal court decisions pave the way for Medicaid funding of AAC devices.

By Lewis Golinker

Major decisions issued by federal courts in Texas and Florida in mid-1996 and by a federal court in Mississippi in mid-1995 significantly strengthen the foundation of Medicaid coverage and funding for augmentative and alternative communication devices.

The court system has rarely been involved in deciding Medicaid coverage for AAC devices and related funding questions. Although there have been thousands, perhaps tens of thousands, of Medicaid claims for AAC devices during the past 17 years, only 11 made their way to court. At press time, only three Medicaid AAC-related court cases were pending anywhere in the United States. This is mostly because at least 45 of the 50 state Medicaid programs decided voluntarily to cover and provide funding for augmentative communication devices or AAC devices, and almost half of those do so with specific AAC funding criteria (see Tables 1 and 2).

Texas attempted to draw a dividing line between children, who could get AAC devices, and adults, who could not.

In most of these states, issues related to coverage and funding overwhelmingly have been resolved through statewide policy changes and the advocacy efforts of speech-language pathologists on behalf of individual claimants.

Although a historic exception, the court decisions in Texas, Florida and Mississippi address issues that go to the heart of Medicaid's duty to cover and provide AAC devices: Are AAC devices "covered" by Medicaid? Are AAC devices "medically necessary"? And is Medicaid the "payer of last resort"?

In the Florida and Texas cases, known as *Hunter* and *Fred C.*, respectively, the issue was coverage: Florida refused to cover AAC deviees for any Medicaid recipients, and Texas claimed it could provide AAC devices to some but not all Medicaid populations. Essentially, the state attempted to draw a dividing line between children, who could get AAC devices, and adults, who could not.

In Mississippi, in a case known as *Myers*, the issue was medical necessity—specifically, whether a state-employed physician, who admittedly knew nothing about AAC intervention, could issue a statewide declaration that AAC devices were never medically necessary.

The Florida case also raised a "payer of last resort" issue. Florida Medicaid that claimed AAC funding for children was never appropriate because other funding programs, such as special education, were required to provide the devices.

The federal courts rejected the states' positions on all of these issues, creating a much stronger foundation for Medicaid funding for AAC devices—and other assistive devices.

One part of that foundation is a straightforward "test," stated for the first time in *Myers* and then adopted by *Fred C.* It requires three distinct questions be asked by therapists and advocates, as well as courts, to analyze Medicaid's duty to cover and fund AAC devices and any form of treatment.

- Is the person who is seeking the treatment a Medicaid recipient?
- Is the treatment being sought covered: Is it within the scope of at least one of Medicaid's covered services?
- Is the treatment being sought medically necessary?

Addressing Coverage

The courts divided the coverage question into two parts. Do AAC devices fall within the scope of at least one covered Medicaid service and, if they do, can a state nonetheless refuse to provide

that treatment? The first question was answered "yes" by all three courts. They concluded that AAC devices fall within the scope of "durable medical equipment," which is a required part of the Medicaid home health care service (42 C.F.R., section 440.70).

The *Fred C.* court went further and also addressed whether AAC devices fit within the definition of the Medicaid "prosthetic device" service, which also is covered by Texas Medicaid. The court said "yes" to this question as well. Currently, prosthetic devices, although an optional Medicaid service, are covered for both children and adults in every state but two (Alabama and North Carolina), and they are the second most common Medicaid service for AAC device classification.

Another benefit of these decisions is that they tie AAC devices—which are equipment—to the two Medicaid services that focus on equipment. Previously, the only court decision reviewing "coverage" of AAC devices concluded they were "equipment," but within the Medicaid "speech-language pathology" service (*Meyers v. Reagen*, 1985). This optional service is covered for adults by only 40 states, and only two states, California and Minnesota, classify AAC devices under this service. Thus, *Fred C.* and *Hunter* provide a more direct connection between AAC devices and Medicaid-covered equipment, and they bring AAC devices within the definition of Medicaid services that are more widely available throughout the United States.

The second part of the coverage inquiry arises because Medicaid programs are not required to provide every conceivable medical treatment or procedure that might fit within a covered service's definition. States have discretion to set the "amount, duration and scope" of the Medicaid services they provide [42 C.F.R., section 440.230(b)], but both *Fred C.* and *Hunter* clearly state that Medicaid cannot exclude AAC devices.

Both courts rejected Medicaid's claim that it had the discretion to limit AAC device access on the basis of recipient age. Both described expressive communication as "vital" and, thus, treatment for this functional ability cannot simply be ignored. Moreover, neither Medicaid program presented anything to show that children had a greater ability to benefit from AAC intervention than adults.

These decisions clearly reject the idea that state discretion or choice will sup-

Table 2.

State Medicaid Programs with ACD Funding Criteria

State	Policy Reference
Arkansas	OMS-91-J-8, Arkansas Department of Human Services (September 4, 1991); OMS-92-J-2, Arkansas Department of Human Services (February 27, 1992)
California	Medi-Cal Policy Statement 96-4: AAC Devices (July 5, 1996)
Illinois	Illinois Department of Public Aid, Informational Notice, Re: Communication Devices (November 1, 1995)
Indiana	470 Indiana Administrative Code, section 5-8-12 (1992)
Iowa	Medical Equipment and Supply Dealer Manual, Chapter E, page 12, paragraph D (October 1, 1988)
Maine	Medical Assistance Manual, section 60, Appendix #3, section XI (A) (December 31, 1991)
Michigan	MSA-94-11, Michigan Department of Social Services (October 31, 1994)
Minnesota	Minnesota Department of Human Services, Medicaid Provider Manual, section 6603.21
Missouri	Memorandum dated July 9, 1993, Missouri Department of Social Services
Montana	Montana Medicaid, Certificate of Medical Need, section 2 (Augmentative Communication Device), Medical Supplies & Equipment Supplier Manual (March 1992)
Nebraska	Nebraska Department of Social Services Manual, 471 NAC, section 7-012 (January 26, 1990)
New Hampshire	New Hampshire Medicaid ACD Funding Criteria (1993)
New York	New York State Department of Health, Guidelines: Augmentative Communication Systems (November 1991), replacing memorandum dated April 18, 1980, to Mr. Williams, Bureau of Ambulatory Care Services, from Mr. Baehm, director, Bureau of Medicaid Standards, New York State Department of Health
North Dakota	Durable Medical Equipment Guidelines, section 5b (May 1989)
Ohio	Ohio Administrative Code, section 5101: 3-1-49 (1993; amended January 1996)
Oklahoma	Position paper on augmentative communication devices, undated
Oregon	Oregon Department of Human Resources, OMAP, section 410-129-220 (1992)
South Dakota	Annotated Rules of South Dakota, ARSD, section 67:02:05
Tennessee	Bureau of TennCare, Chapter 1200-13-12-.01(23) (1994)
Utah	Medicaid ACD Funding Guidelines, February 1, 1993, attached to Letter dated August 7, 1995, to parents of B.S. from L. Stuart, R.N., Public Health Program Manager, Bureau of Coverage & Reimbursement Policy
West Virginia	Department of Health and Human Services, Medicaid Program Instruction, MA-95-47 (November 15, 1995)
Wisconsin	Augmentative Communication System Evaluation; Prior Authorization Guidelines Manual, DME (January 1, 1988)

For a copy of any of these state policies, contact the author.

port age-based distinctions, when there is no accompanying objective medical basis for the exclusion of the treatment in question. This is particularly important for AAC devices, for which perhaps as many as 10 states still attempt to distinguish coverage for children from coverage for adults. On the other hand, the policy reform trend is in the other direction. Since 1994, California, Georgia, Kentucky and New Hampshire, by their own volition; Louisiana, by administrative hearing decision; and Texas and Florida, by court order, have expanded their programs to eliminate child-adult distinctions.

AAC Devices Are "Medically Necessary"

In *Myers*, Mississippi Medicaid conceded that AAC devices are covered as durable medical equipment. But it refused to approve funding for any AAC devices because its review-physician's opinion was that medical need for AAC devices exists only when the message to be produced by the device is "medical," e.g., if the device is "used solely (100 percent of the time) to express 'pain, hunger or medical symptoms.'" Under that interpretation of medical need, AAC devices never are medically necessary, as no person will use an AAC device "100 percent of the time" to convey only medical information.

Since 1988, the Medicaid Act has specifically prohibited Medicaid programs from asserting payer-of-last-resort rules in regard to special education.

The *Myers* court rejected this interpretation of medical need and it provided an extremely broad legal definition of AAC devices: "AAC devices are electronic and non-electronic devices that allow individuals to overcome, to the maximum extent possible, communication limitations that interfere with [their users'] daily activities."

Next, the court reviewed the basis for the Medicaid interpretation of medical need and found it grossly lacking.

At a minimum, Medicaid programs must operate consistently with accepted principles of medical policy, practice and procedure, as demonstrated by objective scientific evidence, not merely the opinions of state Medicaid staff or consultants (*Daubert v. Merrell Dow Pharm.*, 1992). More than a dozen affidavits from nationally respected AAC professionals and AAC professionals from Mississippi described the body of professional literature and current policy and practice related to AAC intervention, and explained that the Medicaid physician's opinion was wholly subjective, uninformed and scientifically wrong. The court then concluded: Although it was the Mississippi Medicaid physician's opinion and it was that doctor's job to make medical need decisions, the decision wasn't correct. And for that reason, it could not be used.

The court threw out the across-the-board exclusion of AAC devices and required Medicaid to make individualized decisions consistent with accepted practice standards and to use a knowledgeable decision-maker.

Payer-of-Last-Resort

The Medicaid program requires that whenever possible, recipients first use other funding sources to obtain needed care. Only if no other sources exist or after benefits from those sources have been exhausted will Medicaid provide its services. This is known as the "payer-of-last-resort" principle.

In *Hunter*, Florida claimed the payer-of-last-resort provisions authorized Medicaid to refuse to provide AAC devices to children on the basis that other funding programs, such as special education and vocational rehabilitation, were required to provide them. The court summarily rejected this argument because, since 1988, the Medicaid Act has specifically prohibited Medicaid programs from asserting payer-of-last-resort rules in regard to special education [42 U.S.C., section 1396b(c)].

The court also stated that while Medicaid can require a recipient to apply first for coverage of a needed treatment from a vocational rehabilitation program, insurance policy or other funding source, if those programs have said "no" or they have not issued any decision at the time the Medicaid claim is filed, Medicaid must pay in full and the payer-of-last-resort rule does not apply [42 C.F.R., section 433.139(c)]. In other words, Medicaid cannot delay its decision-making until the other program decides, and it cannot force a recipient to pursue any appeals or due-process remedies that might be available under those other programs or funding sources.

Conclusion

Viewed together, these decisions reinforce the long-standing assertion that no basis exists for Medicaid recipients needing AAC devices ever to accept "no" as a final answer to their funding requests. There simply is no legal principle that will support Medicaid's refusal to cover and provide AAC devices to any Medicaid recipient when those devices have been recommended by a speech-language pathologist following a careful, comprehensive evaluation. ■

References

Daubert v. Merrell Dow Pharm., 113 S.Ct. 2786 (1992), *see also decision on remand*, 43 F.3d 1311 (9th Cir. 1995).

Fred C. v. Texas Health & Human Services Commission, 924 F.Supp. 788 (W.D. Tex. 1996)(appeal pending).

Hunter v. Chiles, No. 95-6881-CIV (S.D. Fla. Oct. 25, 1996).

Meyers v. Reagen, 776 F.2d 241 (8th Cir. 1985).

Myers v. State of Mississippi, No. 3:94 CV 185 LN (S.D. Miss. June 23, 1995; Order Correcting Final Judgment, October 16, 1995).

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Note: *The Assistive Technology Law Center will provide individualized assistance at no cost to anyone seeking an AAC device or a professional advocating on behalf of a client seeking an AAC device. This assistance applies no matter what the funding source and is available throughout the United States.*

Table 1.

State Medicaid Program Classification of ACDs or AAC Devices

State	ACD/AAC Classification					
	DME	P/D	SLP	REHAB	History of Medicaid payment for ACDs, but classif. is unknown	No history of Medicaid payment for ACDs
Alabama						X
Alaska					X	
Arizona	DME[1]					
Arkansas		P/D[2]				
California	DME[3]		SLP[4]			
Colorado					X	
Connecticut		P/D[5]				
Delaware					X	
Florida	DME[6]					
Georgia					X[7]	
Hawaii						X
Idaho	DME[8]					
Illinois	DME[9]					
Indiana	DME	P/D[10]				
Iowa	DME[11]					
Kansas					X	
Kentucky	DME[12]					
Louisiana	DME	P/D[13]				
Maine	DME[14]					
Maryland	DME[15]					
Massachusetts					X	
Michigan		P/D		Rehab[16]		
Minnesota		P/D[17]	SLP	Rehab[18]		
Mississippi	DME[19]					
Missouri	DME[20]					
Montana					X	
Nebraska	DME[21]					
Nevada						X
New Hampshire	DME[22]					
New Jersey	DME[23]	P/D[24]				
New Mexico						X
New York	DME	P/D[25]				
North Carolina					X	
North Dakota	DME	P/D[26]				
Ohio		P/D[27]				
Oklahoma					X	
Oregon			SLP[28]			
Pennsylvania					X	
Rhode Island						X
South Carolina	DME[29]					
South Dakota		P/D[30]				
Tennessee	DME[31]					
Texas	DME[32]					
Utah		P/D[33]				
Vermont					X	
Virginia					X	
Washington	DME[34]					
West Virginia					X	
Wisconsin	DME[35]					
Wyoming					X	

Footnotes

1. Arizona pays for ACDs under payment code E-1399 (DME not otherwise classified).

2. OMS-91-J-8, Arkansas Department of Human Services (September 4, 1991); OMS-92-J-2, Arkansas Department of Human Services (February 27, 1992)

3. California pays for ACDs under payment code E-1399 (DME not otherwise classified).

4. Memorandum dated July 5, 1996, to Carruth Wagner, M.D., from Medi-Cal Policy Division; "Policy Statement 96-4: AAC Devices" at p. 4-5 (AAC devices fall within SLP services)

5. *In re: T.S.*, Connecticut Department of Income Maintenance (February 19, 1987)

6. *Hunter v. Chiles*, No. 95-6881-CIV (S.D. Fla. Oct. 25, 1996)

7. Georgia's exclusion of ACDs is being challenged (*William T. v. Smith*). See Box.

8. *In re: Stephanie M.*, #93-98-7-4 (Idaho Department of Health and Welfare, April 29, 1993)

9. Illinois Department of Public Aid, Informational Notice re: Communication Devices, Nov. 9, 1995

10. Indiana includes ACD funding criteria in a rule that describes both DME and prosthetic device coverage; 470 Indiana Administrative Code sections 5-8-12 and 5-9-28 (1992).

11. Medical Equipment and Supplier Dealer Manual, Chapter E, page 12, paragraph D (October 1, 1988).

12. Kentucky pays for ACDs under payment code E-1399 (DME not otherwise classified).

13. Louisiana lists ACDs under both DME and prosthetic devices. ACD classification and coverage is discussed in *In re: Betty J.*, No. 405310 (December 22, 1994).

14. Maine Medical Assistance Manual, sections 60.04-2, paragraph 5 (December 24, 1991)

15. DME Supplemental Fee Schedule: Pediatric Medical Equipment & Supplies, page 1

16. Michigan classifies ACDs under both prosthetic devices and rehabilitative services. MSA-94-11, Michigan Department of Social Services (October 31, 1994).

17. *In re: Anonymous*, Minnesota Department of Human Services (April 30, 1985); *In re: William P.*, No. 24396, Minnesota Department of Human Services (October 16, 1990)

18. Minnesota classifies ACDs within speech-language pathology services, which are themselves classified as rehabilitation services. Department of Human Services, Medical Assistance Provider Manual, section 6603.21 (1992)

19. *Myers v. State of Mississippi*, 3:94 CV 185 LN Slip Op. at 5 (S.D.MS., June 23, 1995)

20. Missouri Department of Social Services, letter dated July 9, 1993

21. Nebraska Department of Social Services Manual, 471 NAC 7-012 (January 26, 1990)

22. New Hampshire pays for ACDs under payment code E-1399 (DME not otherwise classified).

23. New Jersey currently pays for ACDs under payment code E-1399 (DME not otherwise classified). See also footnote 24.

24. *In re: Anthony M.*, No. 1360-79 NJ Office of Administrative Law (July 17, 1979); *In re: Kevin K.*, No. 2938-81 NJ Office of Administrative Law (September 1, 1981); *In re: John P.*, No. 7454-82, NJ Office of Administrative Law (December 8, 1982).

25. New York Department of Health, Guidelines: Augmentative Communication Systems (November 1991)

26. Durable Medical Equipment Guidelines, section 5b (May 1989)

27. *In re: Liang-Kuang C.*, #87 SHTO 304 (Ohio Department of Human Services, July 27, 1987; Administrative appeal). AAC devices were an "adequate, workable artificial substitute for a non-functioning larynx." OAC, section 5101: 3-10-20 (prosthetic device codes list); section 5101-2-10-24 (ACD funding rules).

28. OMAP, section 410-129-220 (1992)

29. South Carolina pays for ACDs under payment code E-1399 (DME not otherwise classified).

30. ARSD sections 67:16:02:05 and 67:16:02:05.7

31. Tennessee pays for ACDs under payment code E-1399 (DME not otherwise classified).

32. Defendants' Response to Plaintiff's First Set of Interrog., #4; App. B-11, attached to Plaintiff's Motion for Summary Judgment; Defendants' Supplement to Interrog. Answer #4. Texas pays for ACDs under payment code E-1399 (DME not otherwise classified).

33. Utah Medicaid AAC funding guidelines, February 1, 1993, attached to Letter dated August 7, 1995, to Parents of B.S., from L. Stuart, R.N., public health program manager, Bureau of Coverage and Reimbursement Policy

34. Washington State pays for ACDs under payment code E-1399 (DME not otherwise classified).

35. Wisconsin Medicaid, Prior Authorization Guidelines Manual, W6808 (January 1, 1988)

COMMERCIAL HEALTH INSURANCE PROVIDERS, THE VA, AND OTHER FUNDING PROGRAMS ALL COVER AND PROVIDE AAC DEVICES

INSURANCE

Commercial health insurance coverage and payment for AAC devices began in the late-1970's and currently is widespread.[1]

In 1995, a federal judge noted that hundreds of health insurance providers covered and paid for AAC devices.[2]

Among the insurers that cover and provide AAC devices are:

Aetna	Met Life
Blue Cross/Blue Shield	Prudential
CIGNA	The Travelers

DEPARTMENT OF VETERANS AFFAIRS

The Veterans Administration, now the Department of Veterans Affairs, classifies and provides AAC devices as prosthetic devices.

Veterans Administration coverage and payment for AAC devices began in the mid-1970's.

OTHER FUNDING PROGRAMS

CHAMPUS, covers and provides payment for AAC devices..

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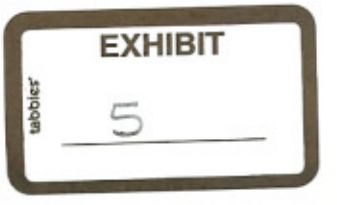
[1] D. Beukelman, K. Yorkston, & K. Smith, "Third-Party Payer Response to Requests for Purchase of Communication Augmentation Systems: A Study of Washington State," 1 *AAC* 5 (1985)

[2] *Myers v. State of Mississippi* (U.S.Dist. Court, S.D.Miss. 1995).



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AAC Augmentative and Alternative Communication

Augmentative and Alternative Communication: An Historic Perspective

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During the past 3 decades, the field of augmentative and alternative communication (AAC) has emerged as a major development for the benefit of individuals with little or no functional speech. This paper attempts to document the social and historic events that led to the emergence of the discipline of AAC and to identify some major milestones in its development. The paper outlines the trends and transitions that have occurred in the areas of aided and unaided communication, intervention, service delivery, consumer issues, and professional development. Although abundant information was only available about the course of development in a few countries, the authors have attempted to use available resources to present the major international events and developments that influenced the evolution of AAC from a North American perspective.

KEY WORDS: chronology, historic perspective, trends

John Gardner observed that "History never looks the same when you're living through it" (1968, p. 86). As members of the field of augmentative and alternative communication (AAC) prepare to meet the challenges of a new century from the standpoint of theoretical and research needs, clinical management issues, service delivery models, technology application, and socio-political advocacy, it is perhaps time to reflect upon past accomplishments. Although history is being made every day, these accomplishments can only be remembered and evaluated if written documentation is available (Beukelman, 1985). By many standards, the field of AAC is still very young. Although much has been accomplished during its short history of several decades, many people are unaware of how the field has evolved. Two factors seem to contribute to this limited awareness of the past. First, much information about the field's development is undocumented; that is, the information resides within the memories of specific individuals who could function as living history books. Second, because significant quantities of other information are recorded within diverse and sometimes minimally circulated print media, the field's existence is unknown or is inaccessible to the many persons with an interest in AAC.

It would be tempting to dismiss this situation of limited historic information as insignificant and focus energies on the present. However, the present has a way of becoming the past. In order for the people involved in AAC to prepare to meet the challenges of a new century, they may wish to reflect upon the ideas and accomplishments of the past before designing new interventions, service delivery models, plans, theories, and so forth. The opportunity to reflect and evaluate, however, presupposes a means for reviewing the history of AAC. This paper represents an attempt to make comprehensive information about the development of AAC accessible to all interested individuals and to provide a benchmark for future documentation.

This paper is not the first attempt at documentation of the field of AAC. Several authors have previously described some aspects of the emergence and development of this new field (Galyas, Fant, & Hunnicutt, 1993; Lloyd, 1980, 1986; Lloyd & Karlan, 1984; McNaughton, 1990; Vanderheiden & Yoder, 1986). These synopses, however, usually recounted events in one particular country or a given continent, or were limited by space constraints that did not permit in-depth documentation with extensive referencing. Although this is true to some degree in the present paper, the present coverage is decidedly more international and the topics more diverse.

Early Years Surrounding AAC Development

Essentially, the field of AAC emerged in the late 1950s and early 1960s as a response to the needs of individuals who, despite years of exposure to what

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Lewis Golinker has 17 years experience with coverage policy reform regarding Augmentative & Alternative Communication (AAC) devices and services and other assistive devices. His experience includes research, writing, and public speaking about coverage and funding for these devices as well as the provision of technical assistance to services providers, advocates and funding program staff.

He has worked to establish AAC device coverage policy with health insurance providers, public education and vocational rehabilitation programs, and with 30 of the 47 state Medicaid programs that cover and provide AAC devices. Lewis Golinker also has worked on assistive device policy reform issues with 31 of the state Assistive Technology Projects and with the providers of assistive technology national technical assistance (UCPA, NAPAS, and RESNA), both of which are funded by the federal Technology Related Assistance for Individuals with Disabilities Act. He has been a consultant to the United Cerebral Palsy Associations on public policy issues related to assistive technology for the past 8 years.

Lewis Golinker participated in writing the AAC Intervention Consensus Statement (NIDRR 1991), and has written more than 3 dozen other articles, book chapters and technical assistance manuals that offer consumers, services providers and advocates comprehensive analyses of Medicaid, public education, vocational rehabilitation, health insurance and Medicare coverage and funding obligations for AAC and other assistive devices.

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