DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Deputy Administrator
Washington, D.C. 20201

JUL 23 1999

The Honorable Ron Packard
House of Representatives
Washington, D.C. 20515

Dear Mr. Packard:

Thank you for your letter to the Administrator regarding Medicare coverage of augmentative and alternative communication (AAC) devices. We agree that these kinds of devices serve an important role in allowing persons with disabilities to communicate. I am responding on her behalf, and I regret the delay in this response.

Your letter addresses relevant points regarding the coverage of AAC devices and the basic issue that the Medicare program does not cover all services that may provide essential assistance or medically related benefits. For example, in general, the Medicare law excludes coverage of the following types of services: dental, eyeglasses, hearing aids, and self-administered drugs. In addition, the Medicare statute is so structured that, while all services must be medically necessary to qualify for coverage, medical necessity in itself does not qualify a service for coverage. Therefore, irrespective of advancements in technology, particular items may not qualify for coverage.

You also mention that the Food and Drug Administration (FDA) classifies AAC devices as prosthetics. It is important to note that the FDA classifications are not reimbursement decisions. FDA classifies medical devices in order to determine the level of regulatory oversight that is necessary both before a device may be marketed and in the manufacture of devices. FDA does not operate under the same statutory provisions and definitions that apply to the Medicare program. For example, the FDA classifies wheelchairs as physical medicine prosthetic devices, while the Medicare statute specifically classifies wheelchairs as durable medical equipment (DME), that is distinct from a prosthetic device for which there is a separate and different benefit category.

We are currently reviewing the underlying analysis of AAC devices again to see whether there is a basis for determining that they are an eligible benefit under Medicare. Specifically, based on our recent review of this matter, we believe that the possibility of coverage under the durable medical equipment benefit warrants further consideration. As part of this review, we have had discussions with the Office of the Assistant Secretary for Planning and Evaluation and other outside experts regarding the characteristics of the population that could benefit from these devices.

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If the Health Care Financing Administration (HCFA) determines this is an eligible benefit, we would then need to determine whether the benefit is reasonable and necessary for Medicare. This process for "reasonable and necessary" determination was published in a Federal Register notice on April 27. This notice is available on HCFA's website.

I hope this information is helpful and, I appreciate your interest in this issue. A similar letter has been sent to the Representative Randy Cunningham who co-signed your letter.

Sincerely,

Michael M. Hash
Deputy Administrator