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Medicare Coverage Process

Review Issues

Augmentative and Alternative Communication Devices (#CAG-00055) Decision Memorandum

To: File: Augmentative and Alternative Communication Devices
CAG - 00055, Reference CIM 60-9 Communicator

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Re: National Coverage Policy Request

Date: April 26, 2000

Medicare is committed to having an open, understandable and predictable coverage process for benefits provided by the program. HCFA relies on medical and scientific evidence to make coverage decisions, including medical literature and data, discussions with medical experts and technology assessments. The agency is committed to striking the appropriate balance between providing timely access to medical advances and ensuring that new technologies and treatments are effective and "reasonable and necessary."

We received a formal request for a national coverage determination on Augmentative and Alternative Communication (AAC) devices. The requestors asked that our current non-covered determination on AACs found in the Coverage Issues Manual 60-9, which is based on Section 1861(n) of the Social Security Act, the definition of Durable Medical Equipment, be deleted and that AAC devices be classified as durable medical equipment and be covered by the Medicare program.

Before a coverage decision could be made, the Center for Health Plans and Providers (CHPP) needed to make an initial determination as to whether or not an item or service falls within a covered benefit category. The decision that AAC devices were "convenience items" and thus did not fit a benefit category had been made a number of years ago. In response to the requestors, CHPP has reversed this decision and has now decided that AAC devices are a Medicare benefit in the category of durable medical equipment (DME).

In order to make a national determination to cover AAC devices, sufficient medical evidence to support such a decision must be presented. Upon review of the supporting documentation presented by the requester, we determined that we need more information to support issuance of positive national coverage guidelines. Until we receive and review additional information, we are reversing our national non-coverage decision, and permitting carriers to make local coverage decisions.

This means that, when this change has taken effect, carriers, as required under Section 1862(a)(1)(A), will make coverage decisions for claims for any AAC devices on either a case-by-case basis or through a local policy. We expect to be able to issue a national coverage decision with detailed coverage guidelines after review of the additional information we are hereby requesting. Until we are able to develop a national policy, local discretion prevails.

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

Of particular note in the supporting documentation, was a 1995 report detailing the recommendations of a workshop sponsored by the National Institute on Deafness and Other Communications Disorders, dealing with AAC research priorities. The recommendations included:

- Study of the influence of user variability on AAC use;
- Development of tools and strategies to validly and reliably measure communicative, operational, linguistic, strategic and social competence of children and adults who use AACs.
- Investigation of the effectiveness of AACs by user age, etiology (of impairment) and social context "to determine those factors that are related to success and failure of AAC use."

The results of the suggested research were not included in the supporting material submitted. We recognize that these devices do not lend themselves to randomized clinical trials, which are the gold standard of scientific evidence, but we need more material reporting results for multiple patients over extended periods in order to develop specific coverage guidelines for AACs.

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

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

Information which can support clinical inclusion characteristics for approval of AAC devices might address the following points:

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

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

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

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

Information that might support development of exclusion criteria might address:

Whether patients with some or all types of aphasia should be excluded from coverage of an AAC device. What types of chronic brain diseases should be excluded? How severe does the chronic brain disease have to be before a patient is incapable of use of these devices? How would we measure or define the severity of chronic brain failure or cognitive function? Should this be determined through neuropsychiatric testing? If so, what test(s) would be accurate, reliable and valid?

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

We would like recommendations as to the number of visits with a speech language pathologist which are necessary for training of the patient in the use of a particular AAC device and in customizing its

features to meet the patient's medical needs.

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

Implementation instructions to contractors will follow and the effective date for this decision will be no later than January 1, 2001.

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