

Comments on Behalf of NACDD
On the Draft National Coverage Determination for
Mobility Assistive Equipment
March 7, 2005

Introduction and Background

These comments are submitted on behalf of the National Association of Councils on Developmental Disabilities (NACDD). NACDD's mission is to provide support and assistance to its Member Councils (State Councils on Developmental Disabilities) in order to promote a consumer and family-centered system of services and supports for individuals with developmental disabilities. NACDD is a national, member-driven organization consisting of 55 State and Territorial Councils. Our organization was formed in 2002 to bring together two national organizations that previously supported State Developmental Disabilities Councils – the Consortium of Developmental Disabilities Councils and the National Association of Developmental Disabilities Councils. We support our Member Councils with implementing the Developmental Disabilities Assistance and Bill of Rights Act, P.L. 106-402 (DD Act).

The DD Act cites a Congressional finding that in 1999, there were between 3.2 and 4.5 million individuals with developmental disabilities living in the US. In the DD Act, Congress refers to a recent study indicating that individuals with developmental disabilities comprise between 1.2 and 1.65 percent of the US population. These figures likely have increased in the last six years. Congress also found in the DD Act that individuals with disabilities “often encounter discrimination in the provision of critical services” and that individuals with developmental disabilities are at greater risk than the general population of abuse [and] neglect.” Of utmost significance to these comments is a Congressional finding that “a substantial portion of individuals with developmental disabilities and their families do not have access to assistive technology...and remain unserved or underserved.”

NACDD is a member of the Washington, D.C.-based “ITEM” Coalition. ITEM is an acronym for **Independence Through Enhancement of Medicare and Medicaid**. The ITEM Coalition was formed in 2003, and its 74 member organizations include a diverse set of disability groups, aging organizations, other consumer groups, labor organizations, voluntary health associations, and non-profit provider associations. NACDD supports the comments submitted under separate cover by the ITEM Coalition.

The following comments will address aspects of the draft National Coverage Determination (NCD) on **Mobility Assistive Equipment** (MAE) as released on February 3, 2005 by the Centers for Medicare and Medicaid Services (CMS). Our comments primarily will focus on the “in the patient’s home” restriction and the omission of “mobility” itself in the list of Mobility-Related Activities of Daily Living.

CMS Failure to Consider Medicare Beneficiaries Below Age 65

NACDD would like to express our disappointment with the apparent failure of CMS to consider the approximately 6 million Medicare beneficiaries with mobility impairments **below the age of 65** in this draft NCD. Virtually every article cited in the draft NCD involves the elderly population. In fact, the draft NCD explicitly acknowledges that it focused on “the elderly” by stating the following in Section II, Background, “Impaired mobility, combined with difficulty in performing mobility-related activities of daily living...places the elderly at risk for a multitude of physiological and psychological consequences that can negatively affect health, well-being, and quality of life.” In addition, Section VIII, CMS Analysis, states “The literature reviewed is...of large sample size (109 – over 40,000) and includes Medicare aged beneficiaries, making the results generalizable to the Medicare population.”

As you know, a “developmental disability” is defined by Congress in the DD Act as: “a severe, chronic disability of an individual that is (i) attributable to a mental or physical impairment or combination of mental and physical impairments; (ii) manifested **before the individual attains age 22.**” Thus, CMS’s failure to evaluate properly the needs of this population is a major oversight. The mobility device needs and functional activity demands of individuals with developmental disabilities often differ starkly from those of beneficiaries who are elderly. This fact should be reflected explicitly in the final NCD. For example, individuals with developmental disabilities require appropriate mobility devices to seek and maintain employment outside the home.

“In The Home” Restriction

NACDD is disappointed that the Agency has decided not to modify the “in the home” restriction through this NCD process. The “in the home” requirement, as interpreted by CMS over the years, essentially confines beneficiaries in need of mobility devices to the four walls of their homes by preventing clinicians from prescribing mobility devices that are appropriate for use outside of the home. This rule is an antiquated restriction, reminiscent of a time when people with disabilities were not expected to leave the home and participate in society. It is an artificial barrier that stands in the way of appropriate wheelchair coverage policy and has far more to do with limiting utilization than it does with any conceivable clinical justification.

By confining the “medical necessity” inquiry to inside the home only, the draft NCD fails to provide adequate access to a substantial number of individuals who are unable to participate in daily life activities that routinely occur outside the home and in the community. A person’s need for an appropriate wheelchair is not confined to the four walls of their home. For example, an individual with a disability such as Cerebral Palsy might be able to walk about inside the home, but still require a mobility device to move safely about their community. Consideration of an individual’s need to access his or her physician’s office, pharmacy, grocery store, place of worship, or return to work should be incorporated into Medicare’s coverage determination process as these constitute a set of reasonable and necessary medical and functional needs.

Of great concern to NACDD is the fact that CMS has stated in the draft NCD that the NCD process is not the “appropriate mechanism to change the [in the home] rule.” However, the NCD fails to state what is the appropriate mechanism to address the ‘in the home’ restriction.

In a letter to the ITEM Coalition (of which NACDD is a member) dated February 17, 2005, CMS stated that the Agency “is comfortable with its interpretation” of the in the home rule. This statement was made in the face of nearly unanimous support by virtually all who commented on the IWWG’s findings that the “in the home” rule was in need of modification and was inconsistent with CMS’s move toward a function-based set of criteria to assess mobility device coverage. NACDD respectfully requests that CMS reconsider its current interpretation of the “in the home” restriction.

The “In-Home” Restriction Is Counter to Current US Policy

The current CMS interpretation of the “in the home” restriction runs counter to numerous US policies and initiatives aimed at increasing community integration and independence of people with disabilities. This archaic interpretation runs counter to major Federal legislation and policy as follows:

- Fifteen years ago, the *Americans with Disabilities Act (ADA)* prohibited discrimination based on disability in employment, public services, public accommodations and in other areas. Mobility device accessibility became the norm. Expectations about living at home and functioning in the community heightened dramatically. Yet, the in-the-home restriction locks in place the medical/functional expectations of disability as it existed forty years ago.
- The Bush Administration’s *New Freedom Initiative*, unveiled just weeks after President Bush initially took office, aims to help Americans with disabilities by increasing access to assistive technologies, increasing the ability of Americans with disabilities to integrate into the workforce, and promoting increased access into daily community life. In fact, the *New Freedom Initiative* listed Medicare’s “in the home” restriction on mobility devices as a policy in need of review by the Department of Health and Human Services. The perpetuation of the “in the home” restriction makes the goal of community integration virtually impossible for Medicare beneficiaries with mobility impairments.
- The Ticket to Work and Work Incentives and Improvement Act (TWIIA) (Public Law 106-170) aims to give Americans with disabilities the ability to choose their own support services and maintain their health benefits when they attempt to leave the disability rolls and return to the workforce. However, in part because of disincentives in Federal law, less than one percent of those receiving disability benefits fully reenter the workforce. The “in the home” restriction and the TWIIA law send mixed messages to people with disabilities. The TWIIA extends Medicare coverage for SSDI recipients who agree to go back into the workforce

but the “in the home” restriction denies them access to mobility devices that are appropriate for use outside the home in the work and community environments.

- In June 1999, the U.S. Supreme Court ruling in Olmsted v. L.C. found that the ADA requires the most integrated community-based settings for individuals with disabilities whenever possible. The Court found that “unjustified isolation is properly regarded as discrimination based on disability.” If the “in the home” restriction does not violate the letter of the law, it seems apparent that the “in the home” restriction violates that spirit of the Olmstead decision by unnecessarily isolating Medicare beneficiaries with mobility disabilities in their homes.

Perhaps of even greater importance is the fact that the “in the home” restriction also lends itself to **increased health and safety risks for people with disabilities** and limits the ability of clinicians to prescribe the safest and most cost effective mobility devices for beneficiaries. A beneficiary’s health, both physical and mental, is wholly intertwined with the ability to be as functionally independent as possible. Any benefit that arbitrarily limits the patient’s functional potential, therefore, unnecessarily places that beneficiary at risk.

The wheelchair-related clinical literature suggests that being confined to one’s home can lead to a number of secondary psychological conditions associated with isolation. Additionally, the outside use of mobility devices deemed sufficient for use indoors has the potential to lead to various physical co-morbidities and potential injuries. For example, it is known that certain patient populations, such as individuals with quadriplegia, degenerative neurological conditions, and poliomyelitis, are at increased risk of experiencing upper limb pain and injury secondary to long term manual wheelchair use. The costs of medically treating these secondary conditions, of course, are very high, but Medicare will cover these expenses with little question.

Functional Ambulation: Activities of Daily Living

By definition, “mobility assistance equipment” or “MAE” is equipment used to aid in mobility. The draft NCD uses the term “functional ambulation” as a measure by which clinicians can assess the need for MAE on behalf of a beneficiary. However, the term “functional ambulation” is defined as “the ability to walk, with or without the aid of appropriate assistive devices (such as prostheses, orthoses, canes or walkers), safely and sufficiently *to carry out mobility-related activities of daily living (MRADLs).*” NACDD finds this definition of “functional ambulation” to go beyond the primary purpose of MAE, which is to supplement mobility in the presence of a mobility deficit, not to aid in the completion of an MRADL.

In fact, as cited in the draft NCD, the items of mobility assistive equipment that are repeatedly referenced in the document (i.e. wheelchairs and power wheelchairs) are specifically categorized in the FDA Code of Federal Regulations (CFR) as follows:

21CFR § 890.3860 Mechanical wheelchair.

(a) Identification: *A mechanical wheelchair is a manually operated device with wheels that is **intended for medical purposes to provide mobility** to persons restricted to a sitting position.* [Emphasis added].

(b) Classification: *Class I (general controls).*

21CFR § 890.3890 Powered wheelchair.

(a) Identification: *A powered wheelchair is a battery-operated device with wheels that is **intended for medical purposes to provide mobility** to persons restricted to a sitting position.* [Emphasis added].

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

NACDD understands that FDA categorizations and definitions technically do not apply to CMS, but these definitions clearly enforce the primary purpose of MAE which is, of course, mobility. NACDD strongly objects to the omission in the draft NCD of “mobility” itself as a mobility-related activity of daily living for purposes of assessing the need for a mobility assistive device. At the Open Door Forum held on February 24, 2005 to discuss this draft NCD, CMS officials stated that the MRADL concept was adopted to focus the coverage determination process on “purposeful” mobility.

But we believe that for a person who spends his or her life without the ability to ambulate, **all mobility is purposeful** and the ability to improve mobility, whether or not it improves the ability to perform some other task, should be considered in the MAE coverage determination process. NACDD believes this omission to be a major failing of the draft NCD. We are concerned that this omission will lead to denials for beneficiaries with a legitimate need for wheelchairs and other mobility devices.

In addition to the glaring omission of mobility itself in the list of MRADLs in the draft NCD, the five Activities of Daily Living (ADLs) selected by CMS to represent the universe of functional abilities relevant for a Medicare beneficiary to perform are highly restrictive and reveal a serious discrepancy between what CMS will consider and the day-to-day needs of Medicare beneficiaries. Of the 700 research articles mentioned in the draft NCD and the 11 actually cited, not one of them defined the term “mobility related activities of daily living” to mean “toileting, feeding, dressing, grooming and bathing.” All of these ADLs are very basic and are performed exclusively in the home setting. There simply is no evidence in the literature or in clinical practice that supports such a limited number and range of ADL functions.

For example, a beneficiary with an upper spinal cord injury may never have the ability to cook for herself or bathe herself independently, even with the use of a mobility device. However, with the appropriate mobility device, the beneficiary may be able to move herself from the bedroom to the computer room where she might be able to read an online newspaper or participate in online classes. She may be able to travel to the kitchen to answer the telephone, move to the bookcase to read a book, move to the front door to pick up the mail, travel to the living room to watch television or move to a patio to visit with a friend.

None of these improvements in function are currently recognized by the draft NCD and every one of them is an example of the basic functional needs of most beneficiaries with mobility impairments.

Conclusion

On behalf of our 55 State and Territorial Councils and individuals with developmental disabilities, NACDD would like to thank CMS for the important work it has done and continues to do to improve the lives of persons with disabilities and their families. We appreciate the opportunity to comment on the draft NCD for Mobility Assistive Equipment. We believe strongly that the existing draft NCD simply fails to address the real-life, reasonable and necessary, medical and functional needs of *all* Medicare beneficiaries, in part, due to CMS's restrictive interpretation of the "in the home" criterion. The Draft NCD asserts that the NCD process is not the proper vehicle to modify the "in the home" requirement, but it does not suggest what the proper process is in order to make such a critical change in CMS policy interpretation.

Further, by failing to include mobility itself as an MRADL and limiting consideration to only those activities of daily living that occur within the four walls or the home, CMS has re-enforced its current archaic interpretation of the "in the home" restriction. NACDD strongly suggests that CMS, in conjunction with publication of the final NCD, publish either a proposed rule or interim final rule that modifies the "in the home" requirement so that Medicare beneficiaries are not inappropriately denied access to the mobility devices they need to be functional and independent.

Should you have any questions about the comments we have submitted or should you require additional information, please do not hesitate to contact me.

Sincerely,

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Cc: Senator Dennis Byars, Chair, NACDD Public Policy Committee