



Comments Submitted by the
ITEM COALITION

To the
Centers for Medicare and Medicaid Services
(CMS)

Regarding the
Draft National Coverage Determination
for Mobility Assistance Equipment
under the Medicare Program

March 7, 2005

Introduction:

These comments are being submitted on behalf of a national, consumer-led coalition known as the “ITEM” Coalition, 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.

The ITEM Coalition’s purpose is to raise awareness and build support for policies that will improve access to assistive devices, technologies, and related services for people of all ages with disabilities and chronic conditions. From coverage for hearing aids to augmentative communications devices (AACs) to advanced artificial limbs to screen readers for people with vision impairments, the Coalition’s mission is a broad one with implications for virtually every person with a disability who relies on assistive devices to be healthy, functional, and independent.

These comments will address several aspects of, and omissions in, the draft National Coverage Determination (NCD) on Mobility Assistance Equipment (MAE) as released on February 3, 2005 by the Centers for Medicare and Medicaid Services (CMS). We have two primary topics on which we would like to comment including the “in the patient’s home” restriction and the standard to be used to replace the “bed or chair confined” language of the existing program guidance. We also have a number of additional comments that we hope you take into consideration when finalizing this NCD.

At the outset, however, we would like to stress 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. In fact, the draft NCD explicitly acknowledges that it focused on the elderly population by stating 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.” The mobility device needs and functional activity demands of this population are often starkly different from elderly beneficiaries and this should be explicitly reflected in the final NCD.

I. The “In The Home” Restriction

A. The Negative Impact of the Restriction:

The ITEM Coalition is extremely 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. An individual with Multiple Sclerosis who is disabled might be able to walk about inside their 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. These needs are just as apparent in the senior Medicare population as they are in the 6 million Medicare beneficiaries under the age of 65.

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. On several occasions the ITEM Coalition has requested that CMS inform the public about the appropriate process through which the "in the home" restriction might be modified, most recently, in an October 2004 letter sent to CMS' Director of Medicare Management as well as in our comments dated January 14, 2005 to CMS on the Interagency Wheelchair Work Group's (IWWG) recommendations.

In a letter to the ITEM Coalition 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' move toward a function-based set of criteria to assess mobility device coverage. The ITEM Coalition, therefore, respectfully requests that CMS' reconsider its current interpretation of the "in the home" restriction for the following reasons.

B. Reasons for CMS to Modify the "In the Home" Restriction:

- 1. The "in the home" restriction was not originally intended to confine beneficiaries to the four walls of their homes but rather to differentiate between the durable medical equipment (DME) that was meant for use in an institution and reimbursed under Medicare Part A, and DME that was intended to be used outside of a hospital or skilled nursing facility and separately reimbursed under Medicare*

Part B. In the Medicare statute, the term “home” is not specified as a geographic location. If the “in the home” restriction were to be applied consistently with the intent of the original Medicare law, mobility devices would be provided to beneficiaries with a medical need as they live in their homes and communities, not simply to those with medical needs exclusively inside their homes.

2. *CMS’ current interpretation of the “in the home” restriction runs counter to numerous Government policies and initiatives aimed at increasing community integration and independence of people with disabilities.*

- 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 and 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.

3. *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 comorbidities 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.¹ Enforcement of the current interpretation of the “in the home” restriction has the potential to deny lightweight manual technology or a power mobility device to someone who is capable of operating a manual wheelchair in their home but who needs a more functional device for outside and community use. Forcing such a beneficiary to “make do” with their “in home” wheelchair in community environments places them at imminent risk of secondary injury to their upper extremities. The costs of medically treating these secondary conditions are, of course, very high, but Medicare will cover these expenses with little question.

II. Deletion of the “Bed or Chair Confined” Standard:

The ITEM Coalition applauds CMS for proposing the deletion of the “bed or chair confined” criterion that is currently used to determine if a mobility device is reasonable and necessary. Additionally, we are pleased to see that CMS is proposing a shift to a functionally-based standard of coverage for mobility devices as the ITEM Coalition believes an assessment of a beneficiary’s functional capacity is a more appropriate means

¹ Curtis, Kathleen, et al., Shoulder Pain in Wheelchair Users with Tetraplegia and Paraplegia, *Arch. Phys. Med. Rehabil.* 80: 453-57 (1999) (“In the current cross-sectional study, both the prevalence and intensity of shoulder pain during the performance of functional activities was significantly higher in subjects with tetraplegia than in subjects with paraplegia.”); Pentland, W. E. and Twomey, L. T., *supra* note 20 (“Wheelchair users whose extremities are already compromised by weakness and muscle imbalance (e.g. quadriplegia, poliomyelitis, degenerative neurological conditions) may be especially at risk [for upper limb pain].”).

of determining medical need for a wheelchair. Functional criteria will better enable clinicians to prescribe the most appropriate and effective mobility device for each beneficiary and may have the added benefit of reducing the risk of injury secondary to the prescription of inappropriate and ineffective mobility devices.

However, functionally-based criteria will ultimately prove to be of little value if CMS continues to administer the Medicare mobility device benefit under its current interpretation of the “in the home” requirement. Significant differences exist between functional limitations inside the home and functional limitations outside of the home. When clinicians are held to assessments of functionality based on activities that are only performed within the beneficiary’s home, they are forced to assess the patient’s needs with “one hand tied behind their back.” This results in the prescription of insufficient and often ineffective mobility devices that fail to meet the real-life needs of Medicare beneficiaries.

III. Functional Ambulation: Activities of Daily Living:

A. Purpose of Mobility Assistance Equipment

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)*.” The ITEM Coalition 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).*

The ITEM Coalition understands that FDA categorizations and definitions do not apply to CMS but these definitions clearly enforce the primary purpose of MAE which is, of course, mobility.

The ITEM Coalition, therefore, 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. The ITEM Coalition believes this omission is a major failing of the draft NCD and is concerned that this omission will lead to denials for beneficiaries with a legitimate need for wheelchairs and other mobility devices.

B. The List of MRADLs is Highly Restrictive

In addition to the glaring omission of mobility itself in the list of MRADLs in the draft NCD, the five ADLs selected by CMS to represent the universe of functional abilities relevant for a Medicare beneficiary to perform are highly restrictive and expose a mismatch 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 bath 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.

C. The Role of the Caregiver in the Assessment Process

The draft NCD establishes a standard for MAE coverage that focuses on the ability to perform MRADLs. But for beneficiaries who may not have the ability to independently perform these ADLs, the NCD states in Section VIII that “the contributions of a caregiver may compensate to overcome the beneficiary’s limitations to operate a wheelchair.”

Additionally, during the Special Open Door Forum held on February 24, 2005, CMS officials stated that a caregiver can be considered during the assessment process if it benefits the patient. Yet the role of the caretaker in the assessment process continues to be very unclear.

The ITEM Coalition is concerned that the NCD creates a rule that in certain situations must be completely waived in order to make sense. Yet the standard that applies when the general rule is waived has not been clearly articulated. The ITEM Coalition, therefore, is concerned that this coverage paradigm cannot be consistently applied and will result in significant confusion in the wheelchair prescription process.

To be sure, the ITEM Coalition agrees with the notion that a caregiver's role in assisting the beneficiary should not operate against the beneficiary in the assessment of need for a mobility device. For example, a beneficiary whose caregiver assists them in bathing should not be denied a wheelchair because the purpose of the mobility – bathing – is not completed independently. However, this exception essentially creates two separate coverage policies; one for those who have caregivers and one for those who do not. Those who have caregivers are actually being assessed appropriately on basic improvement in mobility as any MRADL that is completed with the assistance of a caregiver is considered the result of “purposeful mobility.” However, those beneficiaries who do not employ caregivers' services are being assessed inappropriately on the completion of MRADLs.

The ITEM Coalition simply disagrees that an improvement in the ability to brush one's teeth or comb one's hair, independently or with assistance, should in any way determine whether a mobility device is medically necessary for a beneficiary with a mobility impairment. An improvement in functional mobility itself should be considered an independent criterion that qualifies a Medicare beneficiary for coverage of an appropriate mobility device, considering the totality of the circumstances and functional needs of the individual in both the home and community.

IV. Other Concerns with the Draft NCD

A. Safety Concerns Associated with Wheelchair Prescription

The ITEM Coalition is concerned that the draft NCD does not allow for sufficient consideration of secondary conditions associated with extended manual wheelchair use during the assessment process. Instead, the NCD vaguely requires that a beneficiary “demonstrate the capability and the willingness to operate the device safely.” The draft NCD states that “safety considerations include personal risk to the beneficiary as well as risk to others” and “a history of unsafe behavior in other venues may be considered.” In addition, the algorithmic process outlined in Appendix A of the draft NCD only permits the beneficiary to access a “scooter” or power wheelchair if they are not able to safely use a manual wheelchair. Unfortunately, the draft NCD does not make it clear whether the clinician can explicitly consider the risk of secondary injury to the beneficiary when assessing the safety of a beneficiary to operate a particular mobility device.

Numerous studies have demonstrated that individuals with long term mobility impairments often experience co-morbidities as a result of protracted manual wheelchair use. Clinical studies have shown that prolonged manual wheelchair use is a major factor in the high incidence of secondary injuries to the upper limbs among wheelchair users, resulting in shoulder, elbow, and/or wrist pain.² Additionally, it has been demonstrated that certain patient populations, such as tetraplegics and quadriplegics, individuals with degenerative neurological conditions, and individuals with poliomyelitis, are at an increased risk of experiencing upper limb pain due to manual wheelchair use.³ Unlike most injuries, injuries to the upper limbs among manual wheelchair users are both relatively predictable and avoidable. The injuries are predictable because incidence of upper limb pain has been directly correlated with the time of use of the wheelchair.⁴

The ITEM Coalition recommends that the final NCD and the accompanying algorithmic process explicitly recognize as a “safety” issue the need for clinicians to assess the risk of secondary injuries due to extended manual wheelchair use. We believe inclusion of this concept in the final NCD will not only prevent beneficiaries from experiencing additional injuries and secondary conditions, but will also save the Medicare program from covering the often extensive costs of reparative surgeries and rehabilitation care for these types of secondary conditions.

B. Technical Assessments and Research Disclosure:

The ITEM Coalition recognizes the degree of public participation that the new NCD process allows. However, we are concerned that in this case, the process has not been as transparent as possible. In our comments submitted to CMS on January 14, 2005, the ITEM Coalition requested disclosure of the Technical Assessment used to develop the NCD for mobility assistance equipment. However, as of today, we have not been able to access that assessment. With over 700 clinical articles reviewed during this NCD process and only eleven articles cited in the draft NCD—the vast majority of which only involved elderly populations—the ITEM Coalition is concerned that relevant lines of analysis and bodies of evidence may have been omitted in the development of this NCD.

² Cooper, Rory A., et al., Research on Physical Activity and Health Among People with Disabilities: a Consensus Statement, *J. Rehabil. Res. Dev.* 36(2): 142-54 (1999) (“Manual wheelchair users are particularly susceptible to rotator cuff tears, lateral epicondylitis, and cubital tunnel or carpal tunnel neuropathies due to micro-injury caused by the repetitive motions required to propel themselves.”); Dalyan M., et al., Upper Extremity Pain After Spinal Cord Injury, *Spinal Cord* 37(3): 191-5 (1999) (based on study of patients with spinal cord injury, 71% reported shoulder pain, 53% wrist pain, 43% hand pain, and 35% elbow pain).

³ Curtis, Kathleen, et al., *supra* note 1; Pentland, W. E. and Twomey, L. T., *supra* note 1.

⁴ Nichols, P.J.R., et al., Wheelchair User’s Shoulder?, *Scand. J. Rehabil. Med.* 11: 29-32 (1979) (“One-third had at least one attack of cervico-brachial pain within one year. The frequency [and] duration of the attack tending to increase as time passes. . . . After ten years, 54% have cervico-brachial pain.”)

The ITEM Coalition again requests disclosure of the Technical Assessment as we feel it is important for the public to review and assess the same documents CMS used in the development of this draft NCD. Without those documents, it is extremely difficult for commenters to understand and analyze the basis on which this NCD was created.

V. Conclusion:

The ITEM Coalition appreciates this opportunity to comment on the draft NCD for MAE and encourages CMS to seriously consider not only these comments but the numerous comments submitted by other consumer groups, clinician groups and providers as it drafts the final NCD. In our January 14, 2005 comments on the report of the Interagency Wheelchair Working Group, we expressed our concern about CMS' delay in addressing this issue. While we continue to be interested in an efficient resolution to this unsettled area, we are far more interested in CMS finalizing an *appropriate* NCD than we are in having it completed quickly. The speed with which the draft NCD was published after reception of the January comments and the cursory treatment that the extensive public comments received in the draft NCD raises concerns that CMS is not adequately considering the views of the public during this process. We strongly believe that CMS must address a number of areas that it has, thus far, failed to address if this NCD is going to adequately clarify Medicare mobility device coverage policy.

The existing draft NCD simply fails to address the real-life, reasonable and necessary, medical and functional needs of Medicare beneficiaries, in part, due to CMS' restrictive interpretation of the "in the home" criterion. And no NCD that fails to accomplish this should be published as a final coverage policy of CMS. 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.

It is for this reason that the ITEM Coalition 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.

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 reinforced its current interpretation of the "in the home" restriction. In the face of nearly unanimous and persistent public opposition to the current interpretation of the "in the home" rule, the ITEM Coalition finds CMS' refusal to even address the "in the home" concerns of the public highly frustrating and insufficient. Until CMS addresses this glaring shortcoming in mobility device coverage, the ITEM Coalition believes that mobility device coverage will continue to generate controversy and remain mired in uncertainty and discord.

The ITEM Coalition stands ready to work with CMS and others in good faith to seek resolution of this vexing problem. Thank you for the opportunity to comment on this draft NCD for coverage of mobility assistance equipment.