



January 14, 2005

Elizabeth Truong
Shamiram Feinglass, MD, MPH
Lead Analysts, NCA Tracking Sheet for Mobility Assistance Devices
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Baltimore MD 21244-1850

RE: Comments on IWWG Recommendations Regarding Medicare's Coverage of Mobility Assistance Devices

Dear Ms. Truong and Dr. Feinglass,

On behalf of the ITEM Coalition, please accept the attached comments on the Interagency Wheelchair Work Group's (IWWG) recommendations regarding Medicare's coverage of Mobility Assistance Devices as solicited by CMS in the NCA Tracking Sheet for Mobility Assistance Devices (CAG-00274N) on December 15, 2004.

Please contact us at (202) 349-4260 if you have any questions.

Sincerely,

The ITEM Coalition Steering Committee

Lee Page
Paralyzed Veterans of America

Paul W. Schroeder
American Foundation for the Blind

Kimberly Ruff-Wilbert
United Spinal Association

Kim Glaun
Medicare Rights Center

Peter W. Thomas
CCD Health Task Force

Attached: List of ITEM Coalition Members
Comments of the ITEM Coalition

ITEM Coalition Members

Adapted Physical Activity Council
 Advancing Independence
 Advanced Medical Technology Association
 Alexander Graham Bell Association for the Deaf and Hard of Hearing
 Alpha One
 American Academy of Audiology
 American Academy of Neurology
 American Academy of Physical Medicine and Rehabilitation
 American Association for Homecare
 American Association of People with Disabilities
 American Association on Health and Disability
 American Congress of Community Support and Employment Services
 American Congress of Rehabilitation Medicine
 American Foundation for the Blind
 American Medical Rehabilitation Providers Association
 American Music Therapy Association
 American Network of Community Options And Resources
 American Occupational Therapy Association
 American Physical Therapy Association
 American Speech-Language-Hearing Association
 American Therapeutic Recreation Association
 Amputee Coalition of America
 Assistive Technology Industry Association
 Association for Education and Rehabilitation of the Blind and Visually Impaired
 Association for Persons in Supported Employment
 Association of Tech Act Projects
 Association of University Centers on Disabilities
 Blinded Veterans Association
 Brain Injury Association of America
 Center for Disability Issues and Health Professionals
 Center for Independent Living Inc., Berkeley, California
 Center for Medicare Advocacy, Inc.
 Christopher Reeve Paralysis Foundation
 Consortium of Developmental Disabilities Councils
 Council of Citizens with Low Vision International
 Council of State Administrators of Vocational Rehabilitation
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(202) 349-4260 (phone) ? (202) 785-1756 (facsimile) ? www.itemcoalition.org

Disability Service Providers of America
 Easter Seals
 Epilepsy Foundation
 Families USA
 Goodwill Industries International, Inc.
 Helen Keller National Center
 Inclusion Research Institute
 Long Island Center for Independent Living
 Medicare Rights Center
 The Miami Project to Cure Paralysis
 National Association for Home Care and Hospice
 National Association for the Advancement of Orthotics and Prosthetics
 National Association of Councils on Developmental Disabilities
 National Association of Protection and Advocacy Systems
 National Association of Rehabilitation Research and Training Centers
 National Campaign for Hearing Health
 National Coalition for Disability Rights
 National Council on Independent Living
 National Family Caregivers Association
 National Multiple Sclerosis Society
 National Organization on Disability
 National Rehabilitation Hospital – Center for Health and Disability Research
 National Respite Coalition
 National Spinal Cord Injury Association
 National Stroke Association
 National Vision Rehabilitation Cooperative
 NISH
 Paralyzed Veterans of America
 Research Institute for Independent Living
 Rehabilitation Engineering and Assistive Technology Society of North America
 Self Help for Hard of Hearing People
 Service Employees International Union
 Spina Bifida Association of America
 The Arc of the United States
 Topeka Independent Living Resource Center
 United Cerebral Palsy Associations
 United Spinal Association



Comments Submitted by the
ITEM COALITION
On behalf of 74 Member Organizations

To the
Centers for Medicare and Medicaid Services
(CMS)

Regarding the
National Coverage Determination
For Mobility Assistance Devices
under the Medicare Program

January 14, 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 organizations, 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 from the ITEM Coalition will address not only the Interagency Wheelchair Work Group’s (IWWG) recently released recommendations to the Centers for Medicare and Medicaid Services (CMS) with regard to the prescription of mobility assistance devices under Medicare, but also the process and timeline under which CMS is reviewing Medicare’s wheelchair coverage policy.

Opening of the NCD Process

The ITEM Coalition recognizes the importance of CMS’ recent action to initiate the National Coverage Determination (NCD) process for wheelchairs covered under Medicare as it brings greater formality and organization to the process of review that has been underway for over a year. However, the ITEM Coalition is concerned that this process, which was recently redesigned to permit greater public input and be more responsive in terms of timeliness, will actually prolong problems with access in this benefit category.

On June 14, 2004, CMS held an Open Door Forum during which the IWWG was introduced and a timeline was announced for the review of the wheelchair benefit under Medicare. Draft guidance was scheduled to be released in early October for public comment and final guidance was to be in place by January 1, 2005. However, October and November passed without CMS producing any guidance. Instead, on December 15, 2004, CMS announced that it would be opening the NCD process and the next day released the IWWG’s recommendations for new Medicare coverage criteria for mobility devices. A new call for comments was announced with a due date of January 14, 2005.

The ITEM Coalition is disappointed that a full year after CMS’ wheelchair coverage “clarification” was rescinded after extensive public objection and confusion, and after six full months of internal CMS deliberation, the agency seems to have made little tangible progress in its attempt to redefine its coverage policy for wheelchairs.

Medicare beneficiaries in need of mobility devices are in exactly the same untenable position today as they were over a year ago. In our view, this represents a significant portion of the Medicare population whose mobility needs are at risk of not being met.

The additional delay in crafting new coverage criteria for wheelchairs results in the continuing application of the current coverage criteria, which has the effect of perpetuating inappropriate wheelchair prescriptions and claims denials at the expense of Medicare beneficiaries. While the ITEM Coalition hopes that the NCD review now underway will ultimately lead to improved access, the nine-month timeline announced in the CMS press release dated December 15, 2004 is itself a continuing barrier to access. **The ITEM Coalition calls on CMS to expedite this NCD process as quickly as possible in order to ensure that beneficiaries in need of mobility devices obtain access to them in a timely manner.**

In the Home Restriction

Above all, the ITEM Coalition is extremely concerned by the IWWG's refusal to recommend changes or even substantively address the "in the home" restriction on the Medicare wheelchair benefit. The "in the home" restriction was originally intended to define Durable Medical Equipment (DME) as devices that were provided *outside of an institution* such as a hospital or skilled nursing facility ("SNF") and, therefore, warranted separate reimbursement under Medicare Part B. Unfortunately, over the years, this regulation has been interpreted to restrict coverage only to DME that is reasonable and necessary within the four walls of the beneficiary's home.

The "in the home" requirement, as interpreted by CMS over the years, 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 IWWG recommendations fail 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 a disability like Multiple Sclerosis 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.

According to the Medicare Rights Center’s March 16, 2004 report, *Forcing Isolation: Medicare’s “In the Home” Coverage Standard for Wheelchairs*, by contemporary legal standards, the “in the home” restriction is inappropriate and quite possibly unlawful. The “in the home” restriction runs contrary to promises made in the President’s “New Freedom Initiative,” the Ticket to Work and Work Incentives and Improvement Act (TWIIA) (Public Law 106-170), and the US Supreme Court’s landmark decision, *Olmstead v. L.C. ex rel. Zimring*¹, which established that the ADA prohibits “unjustified institutional isolation of persons with disabilities” and has led to a widespread federal effort to break down barriers to community living for people with disabilities.

Once again, as we have requested many times in the recent past, the ITEM Coalition implores CMS to revisit and revise its current interpretation of the “in the home” requirement and modify it accordingly through this National Coverage Determination process. A failure to do so would constitute another missed opportunity for CMS to enhance access to appropriate wheelchairs and other mobility devices for Medicare beneficiaries with disabilities and other mobility impairments.

IWWG’s Specific Recommendations

After reviewing the IWWG’s recommendations in depth, the ITEM Coalition has several key concerns that are detailed as follows:

1. The Adoption of Functional Criteria:

The ITEM Coalition strongly supports the use of functionally-based criteria for Medicare wheelchair prescription and commends the IWWG for recommending adoption of this new standard instead of relying on the existing “bed or chair confined” standard. The use of functionally based criteria takes into account—to a much greater degree than the “bed or chair confined” standard—the individual circumstances of each person’s condition, physical environment, and mobility potential. 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 prescribe insufficient and often ineffective mobility devices that fail to meet the real-life needs of Medicare beneficiaries.

¹ 527 U.S. 581, 600 (1999).

2. Functional Ambulation: Activities of Daily Living:

The IWWG uses the term “functional ambulation” as a measure by which clinicians can assess the need for a mobility device on behalf of a beneficiary. 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,” also known as “ADLs.” The IWWG then links the medical necessity of a mobility device to the ability to perform ADLs, not to the inability to achieve mobility itself. The IWWG concludes quite clearly that being unable to move from point A to point B unassisted by other devices is NOT an ADL, nor does this inability establish the need for a mobility device in and of itself.

The IWWG report recommends coverage only in those instances where the ability to move from point A to point B through the use of a mobility device will enable the rider to perform some other activity such as bathing, grooming, eating, and other “mobility-related” ADLs. The IWWG’s recommendations specifically state that “a mobility device should be provided with a reasonable expectation that the mobility device will sufficiently remedy the mobility deficit *and* bring about a material improvement in the ability of the beneficiary to complete one or more mobility-related activities of daily living” [emphasis added].

With due respect to the drafters of the IWWG report, the ITEM Coalition views this coverage construct as highly inconsistent, considering the fact that the IWWG report also states that, “Function is particularly relevant because mobility devices are used to compensate for a functional limitation of mobility.” This sentence appears on page one of the report and appears to be contradicted throughout the remainder of the document. We fail to see why the medical necessity of a mobility device should turn on any factor other than the inability to move oneself from point A to point B, whether those points are in the home, throughout the home, around the home, or in the community.

The ITEM Coalition simply disagrees that 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.

It is for this reason that we have two major concerns with the IWWG’s recommendations regarding the functional ambulation standard.

- a. *Beneficiaries with Cognitive or Severe Disabilities:* Individuals with mobility *and* cognitive or severe impairments such as people with

brain injuries, developmental disabilities, and other conditions often experience complications with activities of daily living that are not directly related to their mobility impairment. The same can be said of people with severe physical disabilities like quadriplegia who rely on personal assistants to help them perform all activities of living. A mobility device may not bring about a “material improvement” in their ability to perform a mobility-related activity of daily living; however, such a device could significantly improve their mobility function and thus increase their functional independence. In fact, the IWWG report states clearly that “the provision of a mobility device would not be reasonable” if a beneficiary cannot “successfully accomplish mobility-related activities of daily living.” The ITEM Coalition believes that the NCD must provide for coverage of appropriate mobility devices for individuals with cognitive impairments and severe disabilities who may have difficulty performing ADLs independently but still have a desire and a need to be mobile.

b. *The Use of ADLs:* As already stated, the IWWG report relies on the performance of “mobility-related” ADLs to assess the medical necessity of a mobility device. The report defines the term “mobility-related ADLs,” as “toileting, feeding, dressing, grooming and bathing.” These are very basic and limited functions performed on a daily basis exclusively inside the home. Reliance on this limited list of daily functions in this context constitutes an extremely narrow view of the functions required by the average person to simply live their life, let alone to engage in meaningful activities with family members and others. We, therefore, strongly urge that CMS reject this approach.

We suggest that CMS consider adoption of more realistic functional criteria such as the standard established by the World Health Organization in its International Classification of Functioning, Disability and Health, published in 2001. This functional classification tool would be far more useful to CMS in order to accurately assess the functional needs of beneficiaries with mobility impairments.

Finally, reliance on restrictive functional criteria such as ADLs would eliminate any future chance of modifying the “in the home” requirement as each of the five activities enumerated by the IWWG are performed exclusively in the beneficiary’s home. If an NCD were to be promulgated in final form that did not either modify the “in the home” requirement or accommodate future changes to that restrictive standard, the ITEM Coalition would not be able to support the new NCD. We urge CMS to fully explore other measures of functional capacity in the NCD process, particularly the WHO’s International Classification System.

3. Appropriate Technology:

The ITEM Coalition understands that CMS must employ some standard that dictates the provision of a cane or walker when these devices will meet the basic mobility needs of Medicare beneficiaries without resorting to wheeled mobility. We are also aware that the Medicare program is only obligated to provide coverage for the “least costly alternative” when determining which benefit is appropriate for a particular beneficiary. However, the IWWG report appears to take this concept to the extreme when it states, “The appropriate device for a beneficiary is the one that provides the *least amount of assistance* sufficient to enable the beneficiary to carry out typical mobility related activities of daily living.” [Emphasis added]. If accurate, this is an unfortunate standard to be set by the nation’s largest payer of health care services. One would think that Medicare has an interest in going farther than barely meeting its beneficiaries’ needs. One would hope that Medicare has an interest in providing to its beneficiaries the greatest amount of assistance in a cost-effective manner.

In addition, this policy as applied to wheeled mobility appears to be contradicted by the Medicare prosthetic limb benefit. Under the prosthetic benefit, Medicare has established a series of functional levels that correspond to the functional potential of the individual. The greater the potential of an amputee to function at higher levels, the greater the coverage of technologies that will enhance that ability to function. If the IWWG’s standard were to apply to the prosthetic device benefit, there would undoubtedly be a huge collective decrease in functional capacity of the population of Medicare beneficiaries who utilize lower limb prostheses. This policy suggests that, despite the fact that wheelchairs and artificial limbs can both be described as “mobility devices,” Medicare tends to place greater value on devices that enable beneficiaries to ambulate, rather than devices that substitute for ambulation. If this is true, it is discriminatory and should be rectified in this NCD.

4. Assessment of Home Environment:

The ITEM Coalition supports the IWWG’s recommendation that clinicians carefully assess the beneficiary’s home environment when determining whether (and which type of) a mobility device is medically necessary. The ITEM Coalition supports a full evaluation of each beneficiary’s specific functional needs and physical environment. We also strongly support the IWWG recommendation that the beneficiary’s “diagnosis, personal experience with the disease in their environment, and usual activity level” are key considerations in determining which mobility device is appropriate for the individual.

Despite this language, however, the ITEM Coalition continues to be disappointed by CMS’ and the IWWG’s perpetuation of the “in the home” restriction. While the Coalition understands the need to assess the home setting when prescribing a mobility device, we feel that such an examination should be part of a larger assessment of the patient’s overall environment, both inside and outside of the home, as well as the beneficiary’s willingness and interest to achieve greater functional independence. By confining the clinician’s assessment to the four walls of a beneficiary’s home, CMS

and the IWWG are preventing these experts from prescribing the most beneficial, functional, and potentially cost-effective mobility device.

5. Waxing and Waning Symptoms

In the final paragraphs of the IWWG's report, the issue of waxing and waning symptoms is addressed. Individuals with Parkinson's Disease or Multiple Sclerosis often experience symptoms that wax and wane. The IWWG report states that such symptoms "make it difficult to determine whether or not the beneficiary will benefit from a mobility device" and further describe a "beneficiary who usually walks well" as potentially being "encumbered" by a wheelchair during the time that they are asymptomatic. Additionally, the IWWG report suggests that these individuals, when symptomatic, may not benefit from the use of a wheelchair because their home environmental may not be retrofitted for accessibility (e.g., "heights not accessible by elevators or ramps, exceedingly uneven surfaces").

The ITEM Coalition is very concerned by the IWWG's statements related to the need for people with waxing and waning symptoms to have access to mobility devices. The IWWG's recommendations could essentially deny such beneficiaries access to mobility devices when they are both symptomatic and asymptomatic, for different reasons. The ITEM Coalition fears that the IWWG's recommendations may be interpreted to mean that clinicians should only consider during their assessments the patient's best days in terms of health and functional ability. However, many conditions have fluctuating degrees of severity not only between months and years, but also between hours, days and weeks. Medicare should, therefore, permit clinicians to consider the patient's most severe symptoms and greatest degree of functional limitations during assessments in order to provide the most effective and safe mobility device. Unless this occurs, beneficiaries with waxing and waning symptoms will not have the benefit of the most appropriate device at the very time that the need for it is greatest.

6. Disclosure of the Technology Assessment and Other Documents

In conclusion, the ITEM Coalition would like to request that the IWWG and CMS disclose all information used in the formation of the IWWG's recommendations, specifically the technology assessment commissioned from the Agency for Healthcare Research and Quality (AHRQ), which contracted with ECRI. Additionally, we would ask CMS to recognize that these comments were developed without the benefit of reviewing the technology assessment referenced above, as well as additional comments made by other consumers, clinicians, manufacturers, and suppliers during the previous comment period.

The ITEM Coalition believes it is of utmost importance that the current NCD process be as transparent as possible and encourage CMS to engage in an open dialogue with those invested in Medicare's coverage of mobility assistance devices. We look forward to working with CMS to develop a comprehensive benefit that takes into

consideration the need for Medicare beneficiaries to be as functionally independent as possible.