Introduction

On July 26, 2004, Dr. Sean Tunis, in his capacity as the Chief Medical Officer of the Centers for Medicare and Medicaid Services (CMS), convened the first meeting of the Interagency Wheelchair Work Group (IWWG). He charged the IWWG with reviewing CMS's mobility device prescription policy. The IWWG was asked to evaluate the available evidence on mobility devices, discuss the CMS experience and current policies and implementation practices of other payers, and make recommendation regarding the appropriate prescription of mobility devices.

The appropriate prescription of mobility devices ensures that Medicare beneficiaries who need them will receive them. It also minimizes the likelihood that mobility devices will be provided to people who do not need them or to people who are unable to safely and purposefully use them. The IWWG did not focus on coding, payment, or fraud and abuse issues, which would be better addressed in another forum.

IWWG Panel Members

The IWWG was assembled to comprise clinicians, including physicians, occupational therapists, and physical therapists, researchers, and policy specialists from different federal agencies including the Veterans Administration (VA), National Institutes of Health (NIH), Food and Drug Administration (FDA), Department of Education (ED), as well as different areas within CMS, including the Office of Clinical Standards and Quality (OCSQ), Center for Medicare Management (CMM), Office of Financial Management (OFM), Office of External Affairs (OEA), and Center for Medicaid and State Operations (CMSO). Clinicians, researchers, and policy specialists from these agencies have practical experience with mobility device utilization issues and have brought invaluable expertise and perspective to the IWWG. Furthermore, as evidenced by spirited discussions, the individuals of the IWWG are committed to preserving the dignity and independence of those who must face lost or limited mobility.

Technology Assessment

A technology assessment was commissioned from the Agency for Healthcare Research and Quality (AHRQ), which contracted with ECRI. The IWWG reviewed the evidence and concluded that there is a paucity of methodologically robust published peer-reviewed data pertinent to IWWG's task. In addition, ECRI catalogued current policies and practices by private, state and other Federal payers, as well as a summary of available tools to assess function, which were all reviewed by the IWWG.

Feedback from the Public

CMS received feedback from the public at the Open Door Forum on Wheelchairs held June 14, 2004. Written comments were received from the following:

- Clinician Task Force of the Coalition to Modernize Medicare Coverage of Mobility Products (CMMCMP)
- National Assistive Technology Advocacy Project
- Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition
- Mobility Products Unlimited
- National Coalition for Assistive and Rehab Technology (NCART)
- Pride Mobility Products
- Rehabilitation Engineering and Assistive Technology Society of North America (RESNA)

Functional Criteria

Current CMS manual provisions permit coverage of mobility devices like wheelchairs, power wheel chairs and power operated vehicles only where, "The patient's condition is such that without the use of a wheelchair the patient would otherwise be bed or chair confined." The DMERC's Local Medical Review Policy explains that a patient who is "bed or chair confined" "usually is totally non-ambulatory and has severe weakness of the upper extremities due to a neurologic, muscular, or cardiopulmonary disease/condition." The IWWG recommends that CMS cease applying its "bed or chair confined" standard and adopt new functionally based clinical criteria for mobility device prescribing. Function is particularly relevant because mobility devices are used to compensate for a functional limitation of mobility. Beneficiaries who suffer from a functional limitation of mobility are functionally hindered in their ability to perform mobility related aspects of activities of daily living, such as: toileting, feeding, dressing, grooming, and bathing. They cannot walk to the bathroom to groom and toilet, or to the kitchen or dining room to eat. However, these beneficiaries have sufficient upper extremity strength, coordination, and endurance to perform grooming and toileting functions once they get to the bathroom, and to eat once they get to the kitchen or dining room. In these situations, provision of a mobility device can compensate for the mobility deficit and the beneficiary can obtain a functional benefit.

In contrast, some beneficiaries who experience functional deficits have additional physical and/or mental impediments, such that a mobility device does not enable the beneficiary to realize a functional benefit. Beneficiaries who have serious cognitive or mechanical impairments may be unable to safely operate a mobility device. Similarly, such individuals may be incapable of performing activities of daily living even after being moved to the appropriate location. A beneficiary may live in a structure where the floors or passageways preclude the use of a mobility device. In these examples it would be inappropriate to prescribe a mobility device.

The contributions of a caregiver to the beneficiary's successful use of a mobility device and performance of activities of daily living may be considered in some situations. For example, a beneficiary who is quadraplegic or cognitively impaired may rely on a caregiver who is consistently available, willing, and able to provide appropriate assistance.

The IWWG recognizes that, by statute, Medicare restricts coverage to "wheelchairs…used in the patient's home." Some panel members noted that extending the coverage criteria to explicitly include mobility related tasks performed outside of the home (for example, shopping for food) would facilitate greater functional independence.

Appropriate Prescription of Mobility Devices

An assessment of the beneficiary's physical, cognitive, and emotional limitations and abilities, willingness to use mobility assistance devices on a routine basis, and the beneficiary's typical home environment is necessary to determine the appropriate prescription of mobility devices. In order to facilitate the application of the new functional criteria, the IWWG proposed the following instructions.

Provision of Mobility Assistance Devices Under Medicare Should Include All Five Points Below

- The beneficiary's physical limitations (diminished strength, speed, endurance, range of motion, coordination, sensation, deformity) prevent the beneficiary from accomplishing mobility-related activities of daily living in the home.
- The beneficiary's mental capabilities (cognition, orientation, communication, judgment, memory, comprehension, affect, and suitable behavior) are sufficient for safe and adequate performance of mobility-related activities of daily living with the use of a mobility assistance device.
- The beneficiary's physical capabilities (strength, speed, endurance, range of motion, coordination, sensation) are sufficient for safe and adequate performance of mobility-related activities of daily living with the use of a mobility assistance device.
- The characteristics of the beneficiary's typical home environment in which the activities of daily living are encountered (surfaces, presence or absence of surface accommodations, obstacles, accessibility, changes in grade, and distances covered) are suitable for use of the appropriate device.
- The beneficiary demonstrates willingness to use the device routinely.

The DMERCs may already be applying a similar set of criteria in their application of the present "bed or chair confined" standard. Application of these five criteria requires a consideration of numerous factors concerning a beneficiary's physical, cognitive, and emotional limitations as well as the beneficiary's typical home environment.

Bed or Chair Confined

The IWWG recommends that CMS replace its "bed or chair confined" standard with the IWWG's proposed functional criteria.

Functional Ambulation

Functional ambulation means 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.

Mobility-Related Activities of Daily Living

The determination of functional ambulation status requires an evaluation of whether a beneficiary is consistently able to safely balance and walk at a reasonable rate of speed, without companion assistance, the distances necessary to complete the beneficiary's mobility-related activities of daily living. 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. Such improvements seek to restore functional mobility through the device-assisted augmentation of physical attributes such as strength, endurance, balance, coordination, speed of execution, or joint range of motion.

An individual beneficiary's inability to perform mobility related activities of daily living can have multiple contributing causes, including some that may fall outside of the realm of mechanically impaired mobility. Cognitive, behavioral, and/or sensory deficits or abnormalities may also limit functional ambulation. If these contributory deficits and abnormalities can be compensated for or controlled sufficiently, the additional provision and use of a mobility device may be reasonably expected to materially improve functional mobility. To the extent that these contributory deficits and abnormalities cannot be ameliorated sufficiently such that the beneficiary's ability to successfully accomplish mobility-related activities of daily living is sufficiently restored by the use of a mobility device, the provision and use of a mobility device would not be reasonable.

A beneficiary may have a functional mobility limitation of one or more mobility-related activities of daily living. A mobility device must significantly remedy at least one limitation. The presence of remaining unremedied functional mobility limitations may support the provision of a different mobility device that enhances function to allow completion of a greater number of mobility related activities of daily living.

Safe Use of Mobility Devices

A beneficiary may manifest conditions or behaviors that preclude the safe use of a mobility device. These may be temporary or permanent. Exercise reasonable judgment to determine if the use of a mobility device would present a significant risk that the device would be operated in an unsafe manner. The impact of this factor may vary depending on the specific mobility device being considered, and may require serial reconsiderations during the process of evaluating the beneficiary for mobility assistance.

The manifestation of illness and disability is complex and differs between individuals. The onset and progression of a given disease may result in a range of subjective and objective debility. While disease diagnostic information may portend one or more functional impairments in a class of affected individuals, diagnostic information alone is often insufficient to establish the functional impairment of an individual or the appropriate remedy. Similarly, diagnostic information alone is often insufficient to establish the functional capability of an individual and thereby exclude a potentially appropriate remedy.

Appropriate Technology

An assortment of mobility assistance devices is marketed, including canes and walkers of various designs, manually propelled wheelchairs in various categories, power-operated vehicles such as scooters, and power wheelchairs. 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.

Home Environment

The adoption of the proposed functional criteria would require suppliers and clinicians to make a reasonable attempt to evaluate the beneficiary's home environment. This may be accomplished by personal knowledge or reliable report based on home visits performed by the physician or other health care team member, photographs, drawings, or oral or written description by the beneficiary or a knowledgeable reliable reporter. The effects of prevailing temperature, physical layout, surfaces, and obstacles may be relevant to the determination of the functional limitation of mobility and the determination of the most appropriate remedy.

Assessment of Ambulation and Function

The medical literature contains references to many instruments that assess ambulation and function in a variety of circumstances, such as screening and the monitoring of disease progression. These instruments typically attempt to quantify and classify some combination of factors such as motor skills, personal self-care, continence, mobility, cognitive function, special sensory function, time needed to complete various tasks, disease burden, communication, and mental health. Some instruments require observation of the individual beneficiary's attempts to perform a task in the office by a trained clinician. Others may rely on self-reporting by the beneficiary or family member. To the extent that these instruments may be dependent on the beneficiary's level of effort and cooperation, these factors should be taken into account when the results are used to support the prescription of a device. Results of a validated instrument may inform decisions about the appropriate prescription of mobility assistance devices. Bear in mind that the home environment in which the beneficiary carries out mobility related activities of daily living may differ significantly from the test setting; therefore, make supportable interpretations about the proper applications of the results.

Note the beneficiary's willingness to use a wheelchair on a routine basis, considering the beneficiary's history, the beneficiary's demonstrated cooperation with the functional mobility assessment, and the beneficiary's statements. A device should not be prescribed to a beneficiary if there is sufficient reason to believe that the beneficiary will not make appropriate use of the device.

Some conditions, for example Parkinson's Disease and Multiple Sclerosis, are marked by periods of significant waxing and waning of symptoms. These periods may vary in their predictability, frequency, severity, duration, and amenability to preventive strategies. This makes it difficult to determine whether or not the beneficiary will benefit from a mobility device, and if so to predict the magnitude of any benefit. The duration of symptoms might be so brief that there is little impairment of functional mobility and little opportunity for benefit. A beneficiary who usually walks well might engage in physical activities that are not practically accomplished with a wheelchair, i.e. the beneficiary's function is greater without the use of a wheelchair, which is paradoxically a restriction or encumbrance in some settings. Such a beneficiary might typically experience the onset of functionally disabling symptoms in a setting where the use of a wheelchair is not helpful or practical, and where the wheelchair even if prescribed would not be available for use. Examples might include heights not accessible by elevators or ramps, exceedingly uneven surfaces, etc.

Incorporate knowledge of the beneficiary's diagnosis, personal experience with the disease in their environment, and usual activity level to make a supportable determination about the likelihood that the beneficiary will achieve a materially significant functional enhancement with the device. If less than daily use is likely, a supportable rationale should be provided for the prescription.

Clinical Criteria for Wheelchair Prescribing

The beneficiary, the beneficiary's family or other caretaker, or a clinician will usually initiate the discussion and consideration of wheelchair use. Sequential consideration of the questions below provides clinical guidance for the prescription of a device of appropriate type and complexity to restore the beneficiary's ability to perform mobility-related activities of daily living. These questions correspond to the numbered decision points on the accompanying flow chart.

1. Does the beneficiary have a mobility limitation causing an inability to perform one or more mobility-related activities of daily living in the home? A mobility limitation is one that

    a. Prevents the beneficiary from accomplishing the mobility-related activities of daily living entirely, or
    b. Places the beneficiary at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform mobility-related activities of daily living, or
    c. Prevents the beneficiary from completing the mobility-related activities of daily living within a reasonable time frame.

2. Are there other conditions that limit the beneficiary's ability to perform mobility-related activities of daily living at home?
    a. Some examples are significant impairment of cognition or judgment and/or vision.
    b. For these beneficiaries, the provision of a wheelchair might not enable them to perform mobility-related activities of daily living if the comorbidity prevents effective use of the wheelchair or reasonable completion of the tasks even with a wheelchair.

3. If these other limitations exist, can they be ameliorated or compensated sufficiently such that the additional provision of a mobility device will be reasonably expected to materially improve the beneficiary's ability to perform mobility-related activities of daily living in the home?
    a. A caretaker, for example a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate and transfer the beneficiary to and from the wheelchair and to transport the beneficiary using the wheelchair.
    b. If the amelioration or compensation requires the beneficiary's compliance with treatment, for example medications or therapy, substantive non-compliance, whether willing or involuntary, can be grounds for denial of wheelchair coverage if it results in the beneficiary continuing to have a significant limitation. It may be determined that partial compliance results in adequate amelioration or compensation for the appropriate use of a mobility assistance device.

4. Does the beneficiary demonstrate the capability and the willingness to consistently operate the device safely?
    a. Safety considerations include personal risk to the beneficiary as well as risk to others. The determination of safety may need to occur several times during the process as the consideration focuses on a specific device.
    b. A history of unsafe behavior in other venues may be considered.

5. Can the functional mobility deficit be sufficiently resolved by the prescription of a cane or walker?
    a. The cane or walker should be appropriately fitted to the beneficiary for this evaluation.
    b. Assess the beneficiary's ability to safely use a cane or walker.

6. Does the beneficiary's typical environment support the use of wheelchairs or scooters/POVs?
    a. Determine whether the beneficiary's environment will support the use of these mobility devices.
    b. Keep in mind such factors as temperature, physical layout, surfaces, and obstacles, which may render a mobility device unusable in the beneficiary's home.

7. Does the beneficiary have sufficient upper extremity function to propel a manual wheelchair in the home through the course of the performance of mobility-related activities of daily living during a typical day? The manual wheelchair should be optimally configured (seating options, wheelbase, device weight and other appropriate accessories) for this determination.
    a. Limitations of strength, endurance, range of motion, coordination and absence or deformity in one or both upper extremities are relevant.
    b. A beneficiary with sufficient upper extremity function may qualify for a manual wheelchair. The appropriate type of manual wheelchair, i.e. light weight, power assisted, etc. should be determined based on the beneficiary's physical characteristics and anticipated intensity of use.
    c. The beneficiary's home should provide adequate access, maneuvering space and surfaces for the operation of a manual wheelchair.
    d. Assess the beneficiary's ability to safely use a manual wheelchair.

8. Does the beneficiary have sufficient strength and postural stability to operate a power-operated vehicle (POV/scooter)?
    a. A POV is a 3 or 4-wheeled device with tiller steering and limited seat modification capabilities. The beneficiary must be able to maintain stability and position for adequate operation.
    b. The beneficiary's home should provide adequate access, maneuvering space and terrain for the operation of a POV.
    c. Assess the beneficiary's ability to safely use a POV/scooter.

9. Are the additional features provided by a power wheelchair needed to allow the beneficiary to perform one or more mobility-related activities of daily living?
    a. These devices are typically controlled by a joystick or alternative input device, and can accommodate a variety of seating needs.
    b. The beneficiary's home should provide adequate access, maneuvering space and terrain for the operation of a power wheelchair.
    c. Assess the beneficiary’s ability to safely use a power wheelchair.

Clinical Criteria Algorithm for Wheelchair Prescribing