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Clinician Task Force

January 14, 2005

Elizabeth Truong
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Centers for Medicare & Medicaid Services
7500 Security Boulevard, Baltimore MD 21244-1850

RE: Clinician Task Force Recommended Wheeled Mobility Device Coverage Policy

Dear Ms. Truong and Dr. Feinglass,

The Clinician Task force submits the following recommendations for a new national coverage policy for wheeled mobility devices as invited by CMS in the NCA Tracking Sheet for Mobility Assistance Devices (CAG-00274N) on December 15, 2004. This document includes a list of the Clinician Task Force members and appendices with supportive documents.

Contents:

Introduction:

The Clinician Task Force submits to the Centers for Medicare and Medicaid Services (CMS) the following document for consideration during the agency's development of a new National Coverage Determination for Wheeled Mobility Devices. The goal of the Clinician Task Force is to provide CMS with an objective and consistent process by which medical necessity may be determined and documented.

The 5 core concepts of this proposal are

1. A determination of mobility needs for beneficiaries who live in their own homes cannot be based solely on the needs arising within the four walls of the home. To impose such a limitation is inconsistent with accepted standards of clinical practice, professional policy and professional literature. An assessment so limited will be incomplete and conclusions based on such an assessment will mis-represent mobility needs. No statute directs CMS to develop Medicare policy in a manner inconsistent with professional practice, policy and literature. Mobility needs for community dwelling persons must consider persons' abilities to perform **all** mobility related activities of daily living and instrumental activities of daily living, both inside and outside of the home.

2. A knowledgeable and trained clinician (i.e. a physician, physical therapist or occupational therapist) is needed to perform a face-to-face evaluation of the patient's functional abilities and needs. The comprehensiveness of the evaluation (basic, intermediate, or extensive) and the number of clinical professionals involved depends on the medical complexity and functional needs of the patient. The evaluation results in the clinical determination of the patient's functional mobility level.

3. The key measure in determining medical need for a particular level of wheeled mobility device is based on the patient's clinical evaluation and typical daily function. Focusing on daily function is consistent with Medicare guidelines for other items of DMEPOS, e.g., speech generating devices ("daily communication needs"), and for prosthetic devices, *e.g.*, lower limb prostheses ("expected, post-rehabilitation, daily function"). For wheeled mobility devices, the standard proposed here is the ability to meet the mobility needs arising in the course of typical daily activities. Please note that while the Functional Classification System developed by the coalition is new, it is consistent with current clinical practice. The coalition has merely codified a system.

4, The determination of the beneficiary's potential functional mobility level will be based on the evaluation findings.

5. The next step involves matching the patient's functional level to the appropriate HCPCS coded product.

This document contains mobility device coverage policy recommendations, including:

- Definitions of key concepts used throughout the document including a proposed definition of Functional Ambulation.
- Proposed Coverage and Payment rules which include a Functional Classification System for wheeled mobility device users.

Appended to this submission is additional documentation containing background information on the clinical assessment process for persons needing seating and mobility devices (Appendix A) as well as the roles and responsibilities of the professionals involved in the process (Appendix B). The clinical assessment process outlines the data related to the individual, the environment and the technology. During the recommended clinical evaluation process, seven related topics are assessed:

- the individual's medical history;
- physical abilities and needs;
- functional abilities and needs;
- seating and positioning abilities and needs;
- home accessibility;
- currently used assistive devices; and
- environmental considerations.

Definitions of Key Terms

Functional ambulation means:

the ability of a patient to consistently walk, with or without the aid of appropriate assistive devices (such as prostheses, orthoses, canes or walkers), safely and sufficiently to carry out typical mobility-related activities of daily living or instrumental activities of daily living. Inability to functionally ambulate may be caused by one or more medical conditions causing pain or impairing strength, endurance, coordination, balance, speed of execution, sensation or joint range of motion sufficiently to prohibit functional ambulation.

The determination of functional ambulation status requires an evaluation of whether a patient is consistently able to safely balance and walk at a reasonable rate of speed, without companion assistance, the distances necessary to complete the patient's typical activities of daily living. The patient must also demonstrate the endurance to do these activities. The patient is considered to be "unable to functionally ambulate" if he/she lacks functional ambulation in a setting which the patient would be expected to routinely encounter. (See Appendix A for a list of clinical test used to determine safety and efficiency in sit to stand and ambulation activities.)

Skilled, knowledgeable clinician means:

a licensed physical or occupational therapist or physician who possesses the skills to perform all aspects of the wheeled mobility device evaluation as described.

Mobility needs arising in the course of a patient's typical daily activities means:

mobility that occurs consistently (i.e. regularly) and at a reasonable rate of speed (e.g. normal walking speed), on surfaces typically encountered during the course of a patient's daily activities, and for distances necessary to accomplish the patient's typical daily tasks without pain or excessive signs of fatigue (i.e. dyspnea, discoloration, rapid respirations, diaphoresis, etc.) This includes the patient's need to perform transfers and to use a mobility device to facilitate performance of typical activities of daily living and instrumental activities of daily living.

Accommodated environments means:

ordinary indoor environments and mild outdoor terrain – including smooth, level surfaces (tile or low pile carpet), Americans with Disabilities Act Accessibility Guidelines (ADAAG) compliant ramps (no steeper than 1:12 rise to run ratio), thresholds of less than 1" in height, doorways that accommodate the passage of the wheeled mobility device with an additional 1" of clearance on each side of the device, paved surfaces.

Non-accommodated environments means:

indoor environments with thick carpeting or higher than 1" thresholds or transitions between floor surfaces, outdoor environments with non ADAAG compliant ramps (steeper than a 1:12 ratio) or hills in the natural environment, curbs or gravel, grassy surfaces that are not level.

Rehabilitation technology supplier means:

a specialist who is currently working for a medical equipment company that supplies rehabilitation equipment and employs support staff capable of providing ongoing service and consumer support. The duties of the rehabilitation technology supplier include participating directly in the assessment process by offering a variety of product choices from multiple manufacturers; offering product categories from different product lines; and providing pricing and funding information to the patient and referral sources. The rehabilitation technology supplier also works with manufacturers and/or custom fabricators to combine equipment features to meet specific client needs; provides fittings; and delivers equipment as directed by the referring professional(s). After delivery, the rehabilitation technology supplier provides patients with instruction on how the device works, offers information on maintenance, care, and warranty; and supports the equipment supplied with timely, high quality service.

Activities of daily living (ADL) and instrumental activities of daily living (IADL) mean:

all of the activities a person performs, both inside and outside of his or her home, on a routine (at least weekly). The term “Activities of Daily Living” refers to personal care skills – examples include bathing and dressing oneself and eating. The term Instrumental activities of daily living refers to all other activities that support one’s living that are performed on a routine basis. Examples of these activities include cleaning one’s home, managing finances, shopping for groceries, and retrieving the mail. These examples are illustrative only and are not intended to be an exhaustive list. Both ADL and IADL activities are dependent on the person under consideration and will differ from person to person.

Recommended Coverage and Payment Rules for Wheeled Mobility Devices

AND

A Functional Classification System

FOR

Wheeled Mobility Device Users

Coalition to Modernize Medicare Coverage Policy for Mobility Products (CMMCMP)
Clinician Task Force
www.cliniciantaskforce.org

COVERAGE AND PAYMENT RULES:

For any item to be covered by Medicare, it must: 1) be covered within a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, the criteria for "reasonable and necessary" is defined by the following indications and limitations of coverage and/or medical necessity.

A wheeled mobility device is covered when the patient is unable, due to illness, injury or disability, to functionally ambulate and when all the following criteria (1- 3) are met:

1. Prior to the delivery of the wheeled mobility device, the patient has completed a face-to-face evaluation process conducted by a skilled knowledgeable clinician (as defined above) and Rehabilitation Technology Supplier (as defined above). The formal, evaluation must include at a minimum, the following elements, and the results reported in a written report:
    a. Clinical evaluation
        i. the individual's medical history: including reason for referral, demographic data, primary and secondary diagnoses, onset dates of these conditions, anticipated course of impairments, previous and/or future orthopedic or other surgeries, and history of skin breakdown and treatment intervention.
        ii. physical abilities and needs; including whether the individual's functional mobility needs arising in the course of typical ADLs and IADLs could be met using alternate treatments or assistive devices.
        iii. functional abilities and needs; a description of the functional mobility needs arising in the course of typical activities of daily living and instrumental activities of daily living
        iv. a determination of the patient's ability to functionally ambulate as defined above
    b. Environment and technology survey
        i. environmental considerations; description of home and environmental accessibility, and transportation issues arising in the course of typical daily activities
        ii. currently used assistive devices; a description of currently used devices (e.g. age, condition, type), and equipment trials
    c. Treatment plan
        i. Goal setting and device feature determination; a description of the functional mobility goals arising in the course of typical daily activities expected to be achieved and device features recommended
        ii. Feature and product matching; a description of the rationale for selection of a specific device – matching the person to the

technology, explanation of devices or treatments tried and ruled out
iii. Fitting and delivery; inclusion of a treatment plan that includes fitting and training scheduled for the selected device
iv. Follow up – including plans for training and determination of additional needs

2. A copy of the written wheeled mobility clinical evaluation has been forwarded to the patient's treating physician prior to ordering the equipment; and a copy is kept on file with the supplier, and,
3. The clinician performing the patient evaluation may not be an employee of or have a financial relationship with the supplier of the wheeled mobility device.

BASIC CLINICAL CRITERIA:

Basic Clinical Criteria for Manual Wheelchair Use
The patient is:

1. Unable to functionally ambulate, **AND**

2.
   a. Able to self propel a manual wheelchair adequately to meet the mobility needs arising in the course of typical daily activities, **OR**

   b. Unable to self-propel a manual wheelchair, but not a candidate for power mobility secondary to an inability to safely operate a powered mobility device.

Basic Clinical Criteria for Powered Scooter (POV) Use
The patient is:

1. Unable to functionally ambulate, **AND**

2. Unable to self-propel any type of manual wheelchair adequately to meet the mobility needs arising in the course of typical daily activities, **AND**

3. Able to demonstrate the safe operation of a power mobility device to meet mobility needs arising in the course of typical daily activities, **AND**

4. Able to use upper extremities to control direction of travel through the use of a tiller steering system, **AND**

5. Able to demonstrate the ability to independently maintain good sitting balance without upper extremity support and transfer to the seat safely, **AND**

6. Unlikely, based on diagnosis, prognosis, symptomotology (including rate of change of functional skills) to require a change in steering mechanism, electronic adjustability or seated supports for the lifetime of the device

Basic Clinical Criteria for Power Wheelchair Use
The patient is:

1. Unable to functionally ambulate, **AND**

2. Unable to self-propel any type of manual wheelchair adequately to meet the mobility needs arising in the course of typical daily activities, **AND**

3. Able to demonstrate the safe operation of a power mobility device to meet mobility needs arising in the course of typical daily activities, **AND**

4. Able to operate the power wheelchair with the use of a joystick controller or specialty controller, **AND**

5. Not appropriate, according to clinical criteria, for any type of powered scooter (POV)

Functional classifications of wheeled mobility device users:

The determination that a wheeled mobility device is reasonable and necessary for a patient is based on clinical assessment and judgment by a therapist and the patient's physician, based on the patient's functional abilities, and typical daily mobility needs and based on the following factors:

a) The patient's past history (including prior level of functioning and assistive device use if applicable); and

b) The patient's current condition including present functional mobility status, temporary or permanent nature of condition, static or progressive nature of condition, nature of other medical problems; and

c) The patient's ability to functionally ambulate safely and sufficiently to perform mobility needs arising in the course of the patient's typical daily activities

Clinical evaluation of a patients' mobility potential is based on clinical criteria for manual wheelchairs, powered scooters and power wheelchairs and must be based on the functional classification levels that follow. Clinical evaluation documentation must detail the patient's mobility needs and abilities in the context of typical daily activities.

Manual Wheelchair Functional Classifications (7 Levels)

Level 0: ***(Temporary manual wheelchair user)***

A temporary manual wheelchair user requires short-term wheeled mobility for a condition which prevents functional ambulation

Level 1: ***(Dependent manual mobility user)***

A dependent manual wheelchair user is unable to independently operate any type of wheeled mobility device (powered or manual) **AND**

Uses a wheelchair for limited periods of time, requires a wheeled mobility device solely for dependent mobility, and/or transportation needs **AND**

Does not require a specialty frame for positioning to accommodate for significant postural deformities or allow frequent position changes for pressure management

Level 2: (*Manual wheelchair user with positioning needs*)

A manual wheelchair user with positioning needs requires a specialized wheeled mobility device, to accommodate for significant skeletal deformities and/or, weakness, paralysis or fatigue of head and trunk muscles, and/or skin integrity management, and/or to enhance respiratory, digestive or elimination functions **AND**

Allows for one or more of the following features: changes in seat to back rest angle, **OR** changes in orientation in space **AND**

The wheelchair may be independently operated by the patient **OR** may be a dependent mobility device.

Level 3: (*Light duty manual wheelchair user*)

A light duty manual wheelchair user has a long-term need to perform mobility-related tasks typically in accommodated environments. **AND**

Has the ability and the functional need to independently self-propel, using either upper or lower extremities, or a combination of both, **AND**

Requires minimal adjustable seating configuration to optimize wheelchair propulsion or seated posture; or to accommodate orthopedic deformities, and/or poor trunk/head control, and/or abnormal muscle tone.

Level 4: (*Active long-term manual wheelchair user*)

An active long-term manual wheelchair user consistently and permanently requires a manual wheelchair for community distance mobility. **AND**

Has the ability or potential and functional need to perform both basic and some advanced level wheelchair skills (i.e. negotiating grades, back wheel balancing and curb climbing) to negotiate both accommodated and non-accommodated environments. **OR**

Requires adjustable seating configuration to accommodate or correct orthopedic deformities, optimize seated posture, balance, and stability. **OR**

Requires adjustable frame configuration to optimize wheelchair propulsion, minimize rolling resistance, improve maneuverability and stability.

Level 5: (*Very active, experienced manual wheelchair user who puts great demands on wheelchair frame and parts*)

A very active, experienced manual wheelchair user who puts great demands on wheelchair frame and parts has the ability or potential to perform a number of advanced level wheelchair skills (i.e. negotiating grades, back wheel balancing, propelling in a back wheel balanced position, curb climbing) to traverse non-accommodated environmental barriers. **OR**

Daily functional mobility needs include high activity demands that require wheeled mobility use beyond simple mobility applications including the need to independently load/unload the wheelchair into a vehicle or adjust wheel position to allow for rear wheel balancing. **OR**

Has documented tolerance for a fixed seat position to optimize seated posture, balance, and stability. **OR**

Requires specific wheel and caster positioning to optimize wheelchair propulsion, minimize rolling resistance, improve maneuverability and stability.

Level 6: (*Very active, experienced manual wheelchair user who puts great demands on wheelchair frame and parts with pain or excessive spasticity*)

A very active, experienced manual wheelchair user who puts great demands on wheelchair frame and parts with pain or excessive spasticity is a patient that meets functional classification criteria for Level 4 or Level 5 **AND**

Whose daily functional mobility needs include high activity demands that require a wheeled mobility device with suspension to absorb high force loads from curb dropping and road vibrations causing pain and/or triggering spasticity.

Scooter (POV) Functional Classification: (3 Levels)

Level 0: ***(Light Duty Scooter User)***
A light duty scooter user is a patient whose typical daily activities require mobility in accommodated environments for short distances **AND**

Requires no special seating configurations

Level 1: ***(Moderate Duty Scooter User)***
A moderate duty scooter user is a patient whose typical daily activities require mobility in accommodated environments for medium distance travel **OR**

Requires minimal specialized seating configurations (e.g. non-standard seat size, back angle adjustment)

Level 2: ***(Very active scooter user who puts great demands on scooter frame and parts***)
A very active scooter user is a patient whose typical daily activities require mobility in both accommodated and non-accommodated environments for extended distance travel and may require minimal specialized seating configurations (e.g. non-standard seat size, back angle adjustment)

Power Mobility Functional Classifications: (5 Levels)

Level 0: ***(Power assisted manual wheelchair user):***
A power assisted manual wheelchair user is a patient whose typical daily activities require mobility in accommodated environments **AND**

Is unable to consistently propel a manual wheelchair distances required for typical daily activities **OR** meets clinical criteria for manual wheelchair use but routinely encounters terrains and environments that are impractical or unmanageable with an ultra-lightweight manual wheelchair **AND**

Has the ability to propel the wheelchair via the handrims **AND**

Requires adjustable wheel capability to optimize wheelchair propulsion **AND**

Is able to maintain skin integrity through postural shifts, therefore does not need mechanical method of pressure relief **AND**

There is no indication from diagnosis, prognosis or symptomotology that functional needs will change within the lifetime of the equipment

Level 1: ***(Light duty powered wheelchair user)***

A light duty powered wheelchair user is a patient whose typical daily activities require mobility in primarily accommodated environments **AND**

Has the ability to operate a standard joystick and requires only one drive mode (allows only one set of programmable drive parameters i.e. acceleration, deceleration, turning speed, forward speed, backward speed) with a speed control for safe driving in all environments of use **AND**

No special seating configurations are needed **AND**

Able to maintain skin integrity through postural shifts, therefore does not need mechanical method of pressure relief **AND**

No indication from diagnosis, prognosis or symptomotology that functional needs will change within the lifetime of the equipment

Level 2: ***(Moderate duty powered wheelchair user)***

A moderate duty powered wheelchair user is a patient whose typical daily activities require long distance mobility in accommodated environments **AND**

Has the ability to operate a standard joystick **AND**

Requires multiple drive modes (allows more than one set of programmable drive parameters i.e. acceleration, deceleration, turning speed, forward speed, backward speed) in order to safely drive in all environments of use **AND**

Requires adjustable seating configuration to optimize seated posture, balance, stability or to accommodate skeletal deformity or head and trunk weakness/fatigue **AND**

Is able to maintain skin integrity through postural shifts, therefore does not need mechanical method of pressure relief **AND**

There is no indication from diagnosis, prognosis or symptomotology that functional needs will change within the lifetime of the chair

Level 3 (Active high demand power wheelchair user):
An active, high demand powered wheelchair user is a patient whose typical daily activities require mobility over extended distances in accommodated and non-accommodated environments **AND**

Daily functional mobility needs require a wheeled mobility device with suspension to absorb high force loads from curb dropping and road vibrations exacerbating pain and/or triggering spasticity

Level 4: ***(Powered wheelchair user with complex needs)***
A powered wheelchair user with complex needs is a patient whose typical daily activities require mobility over extended distances in accommodated and non-accommodated settings on a regular basis **AND**

Is at increased risk of pressure sore development due to inability to perform adequate pressure relief technique **AND**

One or more power seating features (tilt, recline, standing) may be needed for pressure relief, bladder management, edema, transfers and/or fatigue **AND**

Uses either a joystick or needs an alternate control system **AND**

May require the use of multiple drive modes for consistently safe mobility **OR**

There is an indication from diagnosis, prognosis or symptomotology that functional needs will change within the lifetime of the chair to require changes in either electronics for drive control or the need for power seating options

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Appendices

Appendix A
Medicare Wheeled Mobility Device Clinical Evaluation

A clinical assessment is required to support all determinations that an individual lacks functional ambulation and therefore requires a wheeled mobility device to meet the mobility needs arising in the course of typical daily activities. An assessment team, consisting of two or more of the following: a physician, clinical professional (such as an occupational or physical therapist) and a supplier, will be responsible for data collection.

The clinical assessment process will gather data related to the individual, the environment and the technology. Seven related topics will be assessed:

- the individual's medical history;
- physical abilities and needs;
- functional abilities and needs;
- seating and positioning abilities and needs;
- home accessibility;
- currently used assistive devices; and
- environmental considerations.

The goal of the clinical assessment is to provide all the data necessary for the professional team to make determinations about the individual's need for a wheeled mobility device and recommendations and prescriptions for the specific device and equipment appropriate for that individual.

For purposes of completeness, the proposed evaluation presents a list of assessment topics and clinical evaluation components in detail. Many of these items will be documented for all individuals who receive a wheeled mobility device assessment. However, some individuals will require a more extensive evaluation process than others, based on unique factors applicable to one or more of the areas of inquiry. The assessment team determines which factors must be assessed and whether additional professionals must be involved.

In addition to the mobility device evaluation, a seating/positioning assessment is often necessary, particularly if sitting balance is impaired or if there are any postural deformities, orthopedic limitations, neuromotor control issues and/or pressure management needs. The seating/positioning evaluation most often will precede the wheeled mobility evaluation as the seating/positioning system must interface with the wheeled mobility base and functional use of wheeled mobility is dependent on appropriate seating/positioning.

The Clinician Task Force strongly recommends the use of a team process for the evaluation and assessment of wheeled mobility devices. A team process founded on effective communication, problem solving, and thorough evaluation is essential to arrive at an appropriate person- technology- environmental match. In addition to the patient and care attendants or family members, the health care team may vary by regional availability or patient needs. Along with the physician may be one or more of the following; the physical and/or occupational therapist who is providing primary care; when needed, a therapist specializing in seating/positioning and wheeled mobility assistive technology;

and a supplier. In some settings, a rehabilitation engineer will also be involved in the assessment process. The physician finalizes and provides all necessary prescriptions associated with the team recommendations.

The outcome of the clinical assessment process is the determination of a treatment plan. That plan includes the need for, and the recommendation and prescriptions of specific equipment and accessories to enable the individual to meet the mobility needs arising in the course of typical daily activities. The treatment plan also identifies the fitting, adjustment, and training services the individual may require to use the equipment to achieve the mobility needs arising the in the course of the individual's typical daily activities.

For all aspects of the Wheeled Mobility Device Clinical Evaluation, the primary care clinician **or** clinical team will determine the required extent of data collection and the specific elements of each evaluation. For purposes of illustration, three levels of evaluation are described. The majority of Medicare beneficiaries will have only basic or intermediate level needs and will not require an extensive evaluation and assessment process. However, a face-to-face evaluation of the patient's functional abilities and needs by a qualified medical professional is necessary to achieve the goals of preventing waste and abuse, even for patients with only basic mobility needs. Patients requiring more advanced powered mobility devices or extensive seating and positioning, will require the more extensive evaluation and assessment process described below. By assuring consistent procedures performed by competent and independent professionals, this more advanced evaluation process will aid in the goals of preventing waste and abuse of the Medicare system – particularly in the provision of powered mobility devices.

Patients with the most basic level of mobility needs – e.g. those requiring basic manual mobility devices with limited degrees of adjustability and simple seating support, will only require a cursory review of the seven major evaluation components (medical history, physical abilities and needs, functional abilities and needs, seating and positioning needs, home accessibility, currently used devices and environmental considerations). These patients typically have good sitting balance and do not have extensive neuromotor involvement. They may be recovering from a temporary medical condition or recuperating from surgical intervention. Often this basic evaluation will be performed by only one medical professional – for example a primary care physician, or a physical or occupational therapist. This evaluation will result in the completion of part B of the Certificate of Medical Necessity and need only determine that the patient is not able to functionally ambulate and requires a basic mobility device for temporary or dependent mobility. This very basic equipment will typically be provided by a durable medical equipment provider or through a pharmacy.

The next level of complexity, the intermediate level, will involve more in-depth review of the seven areas of evaluation (listed above). Examples of these patients include those with ambulation and mobility endurance limitations, typically from non-neurological diagnoses. They have intact or good sitting balance. These patients have simple or no seating and positioning needs but require a means of independent mobility to meet their typical daily functions. They may have arthritic conditions or cardiac and respiratory conditions that prevent functional ambulation and limit overall endurance. Patients in this category typically function in accommodated environments. The brief

evaluation needs to determine the inability to functionally ambulate and whether the patient's needs can be met with a manual wheelchair or not. If a manual wheelchair will not meet the typical daily mobility needs, then enough data need to be collected to determine if a scooter or light duty powered wheelchair is appropriate. The main components of the evaluation remain the same, but a less extensive team process will be needed. Often these evaluations will be provided by a primary care clinician – and may be provided in association with a durable medical equipment or rehabilitation technology supplier. The devices necessary for patients with intermediate level needs may be provided by DME providers or by rehabilitation technology suppliers.

The final level described incorporates patients with complex seating and mobility needs. This is a relatively small portion of the Medicare population and includes those with much more extensive seating and positioning needs. Patients in this category often have neurological disease involvement causing quadriparesis or quadriplegia. They are unable to sit without external support or require support of both hands to maintain sitting balance. These patients will require a much more extensive evaluation process, as described below, and this process should be completed by a team of professionals including a rehabilitation technology supplier. Most will require advanced seating and positioning in addition to mobility assistance. They are also the most active individuals and function in non-accommodated environments on a frequent basis. The evaluation and assessment process described below is most applicable to this final level of patients. While the major areas of evaluation remain the same, the amount or complexity of data within each evaluation area is far greater for the complex level of patient. All possible components or factors to be evaluated are listed and described below.

History and interview

The history and interview process includes:

- referral information
- demographic data
- evaluation of typical daily mobility needs
- medical history
- surgical history
- equipment use history
- functional mobility needs and goals

Each of these areas is described in more detail below.

Referral Information

It is important to note who referred the patient for the wheelchair evaluation (e.g. physician, nurse, social worker, therapist, patient self referral, family member, equipment supplier), the reason for the referral (e.g. impaired functional ambulation), and any other therapy services the patient receives and the purpose of these services (e.g. out patient therapy services, home care services, respiratory services). It is also important to note if the patient uses any other assistive or adaptive devices or communication devices.

Demographic Data

Demographic data includes: patient's height and weight, date of birth, insurance or third party payer information.

Evaluation of Typical Daily Mobility Needs

In order to make an appropriate technology recommendation, data must be collected regarding the patient's mobility needs arising in the course of typical daily activities and any difficulties the patient has meeting these mobility needs. Data also is required regarding the patient's living environment, transportation methods, and caregiver availability. Notes should indicate any recent or anticipated changes in work/home/school status.

Medical History

The medical history includes: primary and secondary diagnoses, onset dates of these conditions, nature of the medical conditions involved (progressive vs. static; acute vs. chronic), current medications used, allergies, precautions, spasticity management interventions, previous and/or future orthopedic or other surgeries, and history of skin breakdown and treatment intervention. It is also important to note any life support systems in use (e.g. ventilators, oxygen, suction) or the future potential need for this equipment. Notes will indicate whether the patient uses orthotic or prosthetic devices while in the wheeled mobility device.

The interview also includes identification and notation of the wheeled mobility technologies currently or previously used by the patient and the patient's preferences and rationale for a future wheeled mobility device. These factors will be subject to comprehensive examination later in the evaluation and assessment process.

Physical assessment

A physical assessment is an essential component for clinical decision making to determine the seating and wheeled mobility prescription. This process allows a clinician to identify seating and mobility problems, assess potential, set goals, and determine the necessary equipment features required to attain those goals. This assessment includes sitting and standing balance assessments, upper and lower extremity range of motion and strength assessments, trunk and pelvic postural assessment, and motor planning, motor control and muscular endurance assessment. If needed, additional elements may include trunk and neck range of motion and muscle strength, skin inspection, sensory testing, muscle tone assessment, testing for presence of primitive reflexes, righting and equilibrium reactions.

A sitting balance assessment is conducted with the patient seated on a mat to determine and document whether the patient is:

- able to weight shift
- able to sit "hands free"
- able to sit with the help of one or two hands, "hands dependent"

- unable to self-support even with use of two hands "externally supported"

More in-depth testing of seated posture and preferred seating body angles are important for a patient who requires significant postural support while using a wheeled mobility device (i.e. hands dependent sitters or those requiring external support to sit). Sitting posture and any abnormalities noted while using the current wheeled mobility device will be assessed and described (e.g. excessive kyphosis or lordosis, scoliosis, posterior or anterior pelvic tilt, pelvic obliquity, pelvic rotation, abnormal hip abduction/adduction or rotation). During this mat assessment, any postural abnormalities are assessed to determine if they are flexible in nature, fixed in nature, or a combination. Specific postural supports designed to either correct a flexible deformity or accommodate a fixed deformity are described at this time.

Joint range of motion, specific to seating and positioning, is necessary to match physical measurements to technology components. These measurements include true hip flexion capability, ability to extend the knees with the hips flexed, and ankle range of motion with the knees flexed. Other measures may be needed depending on the seated posture needs of the patient including trunk flexibility (amount of lordosis, kyphosis or scoliosis) and head control and positioning. During this assessment, body dimensions are needed to determine the size and configuration of the seating support system that will be interfaced with the wheeled mobility device.

A sensory assessment is performed if there are any neurological deficits or if a patient has peripheral vascular disease. This sensory evaluation can include an assessment of light touch, temperature and pain, sensation, and proprioception.

If the patient has any history of skin breakdown, current skin breakdown, or is at increased risk for skin breakdown, assessment of the patient's skin integrity is essential. The location and staging of any current or healed pressure ulcers will be noted. Locations of any healed wounds or surgical scars and tissue or skeletal abnormalities creating at risk sites (i.e. bony prominences) should also be noted.

A pain assessment is indicated if the patient has any complaints related to pain. It is important to note the location of the pain, what causes the pain to worsen, what alleviates the pain. The effect of activities such as walking or wheelchair propulsion on the pain is also critical.

Specific measures that may be useful in the physical assessment include the Short Form of the McGill Pain Questionnaire (SF-MPQ), the Ashworth Score (tone assessment), ROM (goniometry), MMT (manual muscle test), Braden scale or Norton score (pressure ulcer risk assessment) and pressure mapping assessment (pressure assessment).

Functional assessment

Important elements of a functional assessment include:

- cognitive skills assessment
  - memory skills, problem solving abilities, judgment and safety issues, attention and concentration
- vision and hearing status
- functional ambulation ability
- fall history and risk
  - frequency of falls, any known causes of falls, is the patient able to get up following a fall, has the patient suffered any injuries due to these falls – treatments to minimize fall risks
- endurance assessment
  - how long a patient can stand, distance walked before needing to sit
  - how far a patient can propel a manual wheelchair
- description of function on the "best" and "worst" days
  - particularly important for medical conditions that cause fluctuations in weakness or endurance, such as multiple sclerosis
- bed mobility assessment
- transfer assessment
  - transfers from bed to wheelchair, to commode chair, to car;
  - type of transfer used, equipment needed and the level of outside assistance required
- ADL functional assessment
  - bathing, dressing, grooming, feeding
  - should note ADLs performed while seated in the wheelchair
- IADL functional assessment
  - meal preparation, shopping, laundry, banking, household maintenance

Ambulation assessments would be performed without and then with the aid of assistive gait devices. If functional ambulation is not possible, even with an assistive gait device, then the mobility assessment continues using a manual wheelchair. If a patient is already using a wheelchair, then the number of hours of daily wheelchair use is noted. Skills that would be assessed include the ability to propel a manual wheelchair – the type of wheelchair used, the distance propelled, the efficiency or speed of propulsion, and the ability to manage environmental barriers (such as carpeting, door frames, ramps). If a patient is unable to meet the mobility needs arising in typical daily activities using a manual wheelchair, then an assessment for potential use of a power-operated vehicle (POV) will follow. If a POV will not adequately meet typical mobility needs, a powered wheelchair evaluation is required. This includes the ability to operate a standard joystick, the most effective type of alternative controls (if needed), management of doorways, obstacle avoidance skills, management of different ground surfaces, door thresholds, small rises, and overall safety using the device.

If a patient will be using a wheeled mobility device for most of his or her out of bed seating/positioning, then an assessment of his or her ability to perform independent weight shifts is essential in minimizing skin breakdown problems and determining the need for specialty seating equipment.

Specific tests that may be used during the functional assessment include:

- the Timed Get Up and Go Test (fall risk – a score of greater than 11 seconds indicates increased risk of falling),
- Tinetti Assessment Tool (fall risk –a score of less than 23 indicates a risk of falling),
- the Berg Balance Test (fall risk – a score of less than 20 indicates a patient is likely to be unable to ambulate), and
- the Borg Scale of Perceived Exertion (endurance).

Assessment of current equipment (only applicable for patients already using wheeled mobility devices)

A description of the device currently used by the patient is important. The critical factor to assess is the ability of the current device to meet the mobility needs of the patient arising in typical daily activities. However, other information impacts the technology recommendation as well such as, the status (i.e. rental, purchased, loaner equipment) and condition of the seating/positioning system and wheeled mobility device. In addition, information regarding the age of the equipment is obtained, or problems associated with the use of the device are described. The person responsible for caring for this equipment is identified and asked for input regarding necessary features of a new device. The positive and negative features of the current equipment are noted. The reason why the current device is no longer meeting the patient's needs is determined (e.g. changes in the patient's condition, age and wear and tear on the equipment, etc.) and any changes/modifications required specified. Mobility equipment that was tried in the past is noted and reasons for failures of these devices to meet the patient's needs are identified.

In addition to the current wheeled mobility technology used, any other assistive devices used by the patient are described – including environmental control systems, life support systems, and communication or speech generating devices. Compatibility and interfacing requirements of this other equipment will need careful consideration in determining the features of a new device.

Home environment and transportation survey

If a patient is determined to require a wheeled mobility device through this evaluation, then a home access survey is needed. When performing the home access survey, it is preferable to assess mobility and function using the recommended equipment. If more than one device is under consideration, then a home assessment using each type of alternative device is indicated in order to determine which best meets the goals of use.

Items to be reviewed include entrance/exit requirements (i.e. ramps, stairs, elevator), general layout of the home environment, doorway widths including all doors used by the patient (i.e. bedroom, bathroom, living area), access to sink, commode, tub/shower and kitchen, floor coverings (carpet, rugs, etc.), threshold heights, bed height, other chairs used by the patient and seat height/configuration.

In addition to the physical layout of the home, the roles and responsibilities of the patient in the home setting are determined. In addition, any caregiver assistance available in the home is noted (this includes identification of the caregiver, how many hours they are available, and any physical limitations of the caregiver).

The patient's current roles and typical daily activities outside of the home are noted including environments that he/she needs to access to perform these roles and activities (i.e. access to grocery store, work environment, and workstation access).

It is important to consider how the patient will transport the mobility device in the community. The following questions may help guide this assessment:

- Will the device be transported in a personal vehicle? (car or van)
- How will the device be loaded into the vehicle?
- Will the patient be a passenger or driver in this vehicle?
- What is the accessibility of the vehicle? (i.e. car vs. adapted van with a ramp or lift)
- Will the patient use public transit – fixed route or paratransit system?
- Will the patient ride while seated in the wheeled mobility device?
- What restraint system will be needed?
- What other forms of travel will be used? (e.g. trains, cabs, etc.)

Treatment plan

For a patient with impaired ambulation or mobility, several different goals and treatment interventions may be applicable. Goals may include: evaluation of ambulation aids (e.g. canes, walkers), improvement of balance through therapeutic or medical intervention, improvement of ambulation through treatment intervention, or functional training related to mobility, transfers, ADL or IADL functions. These will all be goals related to specific therapeutic treatment interventions, usually determined by physical or occupational therapists under direction of a primary physician.

If traditional therapeutic intervention or the application of ambulation aids will not allow a patient to meet the mobility needs required by typical daily activities, then goals and interventions related to wheeled mobility device use will be required. The intervention will include functional assessment for a seating/positioning and wheeled mobility system, including recommendations for trial and training with a specifically chosen wheeled mobility device. These aspects of the service delivery process are described in more detail below.

Determination of equipment recommendation

Following the evaluation process described above, several steps in the process of determining needed seating/positioning and wheeled mobility device intervention still remain. These steps are listed and briefly described below. A comprehensive service delivery program contains all of these elements and optimizes device selection and outcomes of the intervention.

Goal Setting and device feature determination

In goal setting and device assessment process, consideration of the unmet mobility needs arising in the course of typical daily activities is critical. The wheeled mobility device will be responsible for bridging the gap between the patient's functional mobility level and his or her functional mobility needs. The patient and critical caregivers, working with the physician and therapists, determine mobility goals. Goals for mobility should also include a determination of the functional classification of the patient's mobility. Features of technologies that meet the identified goals are determined based on the assessment information and the patient's goals.

Feature and product matching

Once there is a determination regarding necessary mobility device features, the clinical team members consult with the DME supplier, regarding products available that have the recommended features. In the case of technology that is more complex or requires multiple interfacing of devices, the RTS, that has knowledge and experience with rehab technology will be consulted. As often as possible, "demo" equipment is tried before making a final product selection. Once determined, the final device specifications are recorded, priced and a prescription and letter of medical necessity are generated.

Fittings and delivery

Once recommendations are completed and if available, funding prior approval or advanced determination of medical coverage obtained, a supplier or RTS orders, receives and assembles the devices. Then the devices are delivered and adjusted to meet the postural support and functional mobility needs of the patient. The clinician will determine during treatment planning and goal setting whether the level of recommended technology will require one or more fittings. The delivery process will be performed based on instructions from the same team involved in the assessment process. This may involve the return of the patient to the clinical setting for fitting and delivery or a visit to the patient's home environment by the supplier and the clinician. As most technologies have some level of adjustability, the fit and function is achieved through this process.

Training

There are two different types of training required. Training on how to functionally use the device to meet functional goals, and training regarding how the device works i.e. how to engage a wheel lock or how often to change batteries. Wheeled mobility devices, particularly powered mobility devices, require education and training for optimal use by the patient. This is essential for maximum safety and independence with mobility. In all cases it is critical to train the patient, caregivers or family members in proper use and maintenance of equipment.

Determination of outcomes

Following delivery and training with the device, a determination of outcomes or the ability of the device to meet the goals established at the time of the assessment is made. This can be done during the training sessions, through a follow up questionnaire, phone consultation, or re-evaluation visit.

Follow up program

The patient's seating/positioning and wheeled mobility device needs often change over time, particularly in the presence of aging, changes in body size or weight, a progressive medical condition, or significant changes in the individual's typical activities. Modification of existing technology or evaluation for new technologies may be needed. Assessment programs often have monitoring methods in place and patients will return for modifications to current technologies or new device evaluations as needed.

Appendix B

Roles and Responsibilities of Participants in the Wheeled Mobility Device Service Delivery Process

Determination of the need for a wheeled mobility device and the selection and fitting of appropriate equipment requires collaboration among professionals with a wide range of knowledge and experience. These include: medical professionals; clinical professionals (such as occupational and physical therapists); and rehabilitation technology suppliers.

Initially, their responsibility is data collection. A comprehensive physical evaluation is at the heart of a process that will generate data related to the person, technology and environment. Clear role delineation at this step: what data are most appropriately and efficiently by the clinical team, or by a supplier, will ensure all the necessary data are gathered, and that the process is implemented in a cost effective manner.

Next, these data are used for clinical decision making and equipment specification. The equipment specification must then be applied to the coverage and payment rules so that appropriate wheeled mobility device recommendation and prescription determinations are made. Here, too, defining participant roles, including the responsibility for data sharing, and identifying decisions for which a team or collaborative effort is most appropriate, will ensure that the ultimate conclusions, recommendations and prescriptions are credible and deserving of Medicare funding.

In addition, it is essential to both the quality and integrity of the process that those involved have appropriate training and expertise. For example, the term rehabilitation technology supplier (RTS) is used throughout this document. The term RTS is used to distinguish between a supplier of standard DME and a supplier of rehabilitation technology. The rehabilitation technology products and services provided by a RTS far exceed the scope defined by durable medical equipment (DME). Not only are the products more specialized and designed to accommodate the unique medical and functional needs of individuals with complex disabilities, the clients themselves are different as well with more complex seating and wheeled mobility needs. There are very specific distinctions such as certification of individuals that have very specific training, experience, follow an established code of ethics and complete annual continuing education that allow patients, their families, and caregivers as well as CMS to identify a qualified RTS.

A similar analogy exists for clinicians. There are clinicians that have special training in the area of assistive technology and who are uniquely qualified to assess the needs of more complex individuals with the most sophisticated positioning and mobility needs.

ROLE DELINEATION

There are varied wheeled mobility device service delivery models utilized across the United States involving collaboration among professionals with a wide range of knowledge and experience including: medical professionals, clinical professionals (such

as occupational and physical therapists), rehabilitation technology suppliers and DME suppliers. Consequently the party responsible for completing components of the service delivery process differs. The "team" referred to in the following discussion consists of, at a minimum, a single clinician and a supplier – either a DME supplier or an RTS. For more basic levels of evaluation, a simple team is all that is required. The more complex the needs of the patient, the higher number of team members involved.

It is critical that a skilled and knowledgeable clinician complete certain elements of the process. A DME supplier can complete some elements while other elements are more appropriate to be completed by a RTS. As described below, many of the elements of the service delivery process are shared responsibilities, handled as a team; other elements need to be assigned to a responsible party, completed and then shared among all team members.

History and interview

It is important to obtain all the required information. It is less important to designate who gathers specific information or even whether an employee of the medical facility or the supplier gathers it. What is critical is that the information is shared. Oftentimes, multiple team members gather 'history and interview' information allowing for comparison of findings and identification of inconsistencies.

Physical assessment

A skilled, knowledgeable clinician must complete the elements of the physical evaluation. However, measuring body dimensions is one step in the assessment where the patient is best served with a team approach. The eyes of both perspectives are valuable. In addition, the supplier carries the financial liability if the resulting equipment order is incorrect. Therefore, it is important for the supplier to participate during this process.

Functional assessment

A skilled, knowledgeable clinician should also complete the functional assessment. There is one exception to this as well. A team approach is recommended when evaluating the patient's mobility skills using different types of equipment and the patient's current technology if they currently use wheeled mobility. However, the clinician has the responsibility of documenting the results of this assessment.

Home environment and transportation survey

The most qualified member of the professional team (supplier or clinician) will complete this survey. It should be agreed to, upfront, who will be responsible for completing the survey and the information gathered must be shared with the entire team. The resulting technology recommendation is only appropriate if it will function in the environment(s) that the patient will use it to perform typical daily activities.

Treatment plan

This is the responsibility of the clinician(s) involved with the patient.

Goal Setting and preliminary device feature determination

In situations where seating and positioning goals and complex mobility needs are identified, a team approach, including a skilled and knowledgeable clinician and an RTS is recommended. It is the combined knowledge regarding the patient, the patient's goals and the technology that will produce the best outcome.

Feature and product matching

The DME supplier or the RTS is responsible for matching the technology requirements identified through the assessment process with the available features of a specific technology solution. Through knowledge of the technology, catalog review and communication with manufacturers, the supplier will present a specific product(s) recommendation. A RTS will be required when modification of technology, highly configurable technology or when multiple technologies must be combined in order to meet the patient's needs.

Fittings and delivery

If the clinician determines that the level of technology required to meet the functional needs of the patient will necessitate fittings or adjustments, a fitting involving the original assessment team will be recommended before the final delivery. This will allow the clinician to verify that the recommended technology meets the functional needs of the patient. If any additional needs or modifications are identified these issues can be addressed. If the recommended mobility device does not require custom fittings or adjustments, then equipment assembly and quality checks can proceed and the equipment delivered to the patient's home by the supplier.

Training

It is the responsibility of the clinician to teach a patient how to use the technology to meet the identified functional goals. The clinician also will teach a patient how to safely perform activities such as transfers, obstacle climbing, traversing various terrains etc. The supplier however, is responsible for educating the patient, caregivers and family members on the proper care and maintenance of the device. In addition, the supplier demonstrates the proper use of the equipment such as how to engage a wheel lock, how to charge batteries etc.

Funding

In the Medicare model, funding occurs after the final delivery of the equipment. However, there are steps that occur throughout the service delivery process that are critical to the final submission of a claim. The clinician will develop the Letter of

Medical Necessity (LMN) and, in many cases, complete section B of the Certificate of Medical Necessity (CMN). If denials occur, the clinician will often be involved in gathering additional documentation needed to demonstrate medical need. The supplier develops the cost statement for the technology solution, and completes section A and C of the CMN. There are many other funding steps completed by the supplier in attempts to determine medical coverage or explain limitations of coverage to the patient. The supplier is responsible for completing or assisting with the appeals process.

Determination of outcomes

Both the clinician and the supplier will determine whether the desired mobility outcomes and functional goals have been met. The clinician may want to ensure that the patient is satisfied with the device and the supplier. Additionally, the supplier will attempt to verify customer satisfaction regarding the supplier's role in the service delivery process.

Follow up program

The clinician will establish recommended therapeutic follow up during the treatment-planning phase. The professional team will need to be involved if modifications, adjustments or fittings are required, that will change the original specifications recommended by the clinician. The supplier will conduct maintenance and service, as well as adjustments that will not modify the clinicians' original recommendation.