

APPENDIX A

Clinical Criteria for MAE Coverage

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 equipment 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.

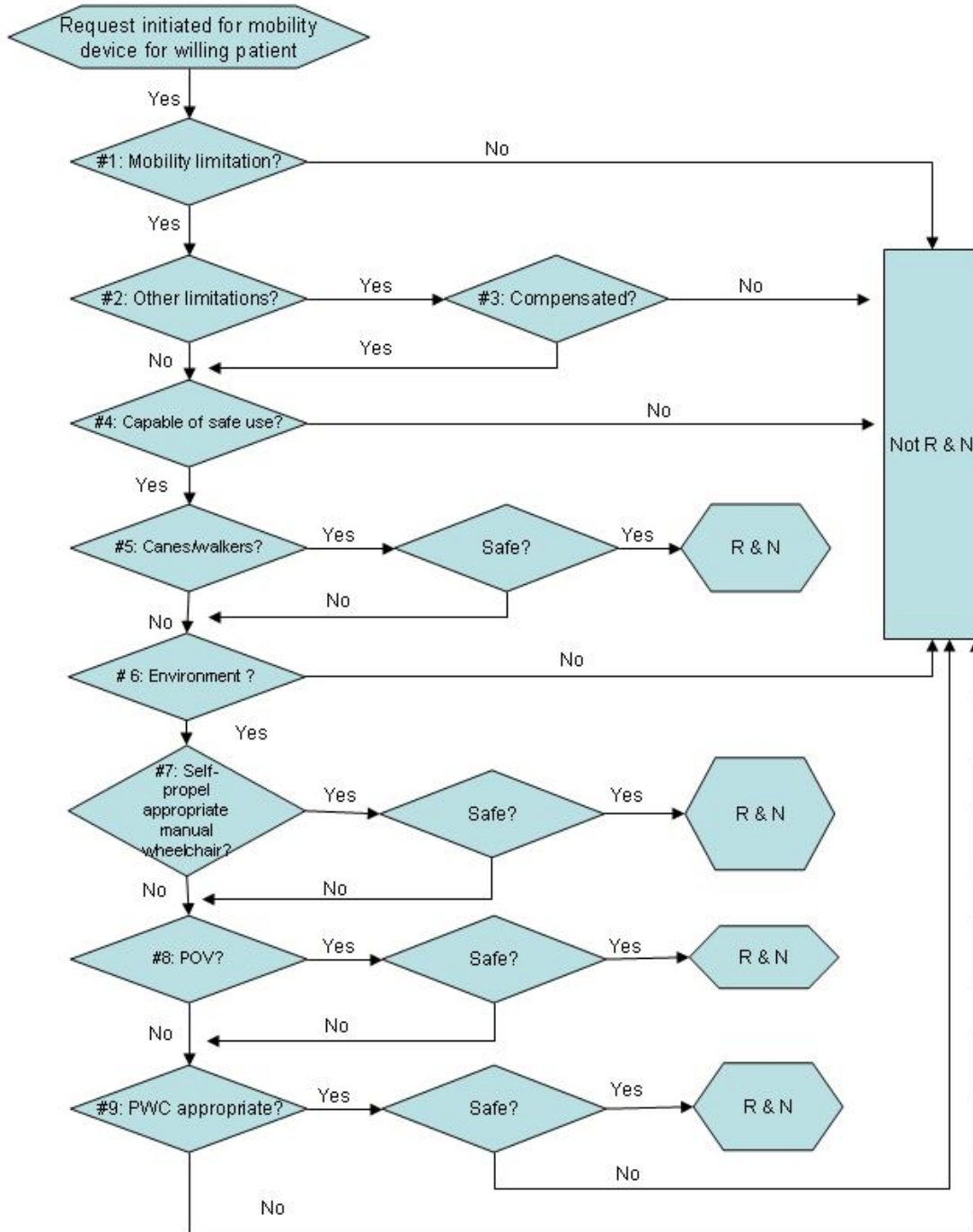
2. Are there other conditions that limit the beneficiary's ability to perform mobility-related activities of daily living at home?
 - a. Some examples are significant impairment of cognition or judgment and/or vision.
 - b. For these beneficiaries, the provision of a wheelchair might not enable them 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 mobility equipment 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. The caretaker's need to use a wheelchair to assist the beneficiary in the mobility-related activity of daily living is to be considered in this determination.
 - 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 mobility assistive equipment.

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 types of mobility equipment.
 - b. Keep in mind such factors as temperature, physical layout, surfaces, and obstacles, which may render mobility equipment 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 for MAE Coverage



APPENDIX B

General Methodological Principles of Study Design (Section VI of the Proposed Decision Memorandum)

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve net health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the generalizability of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

Assessing Individual Studies

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematic assessment of factors related to outcomes.
- Larger sample sizes in studies to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to which group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is the extent to which differences between intervention and control groups can

be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).
- Co-interventions or provision of care apart from the intervention under evaluation (performance bias).
- Differential assessment of outcome (detection bias).
- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are important factors as well. For example, a well designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in which confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and consider the evidence.

Generalizability of Clinical Evidence to the Medicare Population

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to which the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider). Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage determinations for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. One of the goals of our determination process is to assess net health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

Assessing the Relative Magnitude of Risks and Benefits

In general, an intervention is not reasonable and necessary if its risks outweigh its benefits. Among other things, CMS considers whether reported benefits translate into improved net health outcomes. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

APPENDIX C

Evidence Tables

Study	Study design	MAD	Methods	Patient population	Conclusions
Taylor and Hoenig 2004(24)	Retrospective analysis of data from a cohort study	Wheelchair, walker, cane	Data from the Asset and Health Dynamics Among the Oldest Old database were studied	8,222 community dwelling individuals older than 70 years of age	40% of those using assistive devices (including wheelchairs) reported experiencing difficulty in independently performing ADL even with the aid of the devices. Only 4.4% of those who did not use any assistive devices reported experiencing difficulty in independently performing ADL. Persons reporting difficulty in performing ADL reported requiring significantly more hours of personal assistance than did persons reporting no difficulty in performing ADL. The activity most commonly reported as difficult was transferring.
Agree and Freedman 2003(25)	Retrospective analysis of data from a cross-sectional survey	Cane, walker, wheelchair, crutch	Data from the Disability Supplement to the 1994-1995 National Health Interview Phase 2 Survey were analyzed	Less than 17,920 but more than 7,051 (total number not clearly reported) adults reporting difficulties in performing ADLs	Even after adjusting for underlying level of disability, users of assistive technology devices report that tasks are tiring, time consuming, or painful as often as non-users of assistive technology devices.
Hoenig et. al. 2003(26)	Retrospective analysis of data from a cross-sectional survey	wheelchair, cane, walker	Data from the 1994 National Long Term Care Survey were studied using multivariate models	2368 community dwelling individuals older than 65 years of age, with 1 or more limitations in ADL	There was a strong and consistent relation between use of technological assistive devices (including wheelchairs) and requiring fewer hours of personal assistance to perform ADL.
Hammel et. al. 2002(27)	Cohort study	not specified	Patients were evaluated and provided with assistive devices, then re-evaluated three years later	109 adults with developmental disabilities (mental retardation and/or cerebral palsy). Approximately half lived in the community; the rest lived in institutions	At the first time point, over 70% of subjects were found to have higher ADL function with the use of the prescribed assistive devices. Over time, functional ability without the use of the assistive devices did not change. 14% of subjects had higher functional ability with use of the assistive devices at the second time point. Subjects living in the community had higher ADL function than subjects living in institutions, with or without assistive device use.

Study	Study design	MAD	Methods	Patient population	Conclusions
Verbrugge and Sevak 2002(28)	Retrospective analysis of a cross-sectional survey	not specified	Data from the Disability Supplement to the 1994-1995 National Health Interview Survey were analyzed	41,225 individuals aged 55 or older	Poor overall health is correlated with use of personal assistance in performing ADLs. Severe difficulty in performing ADLs is correlated with use of equipment for assistance in performing ADLs.
Allen et. al. 2001(29)	Retrospective analysis of data from a cohort study	Cane, walker, wheelchair, crutch	Data from the 1994 and 1995 Adult Followback Survey of the Disability Supplement to the National Health Interview Survey were studied using regression analyses	9,230 adults with limitations in ADL and mobility	Adults who used wheelchairs had, on average, 8.6 (on a scale of 1 to 15) limitations in ADL/IADL. Adults who used other mobility assistive devices had, on average, fewer limitations in ADL/IADL: walkers- 7.6, crutches- 6.0, and canes- 5.5. Adults who did not use mobility assistive devices had, on average, 3.5 limitations in ADL/IADL. Use of canes and crutches, but not walkers and wheelchairs, reduced the hours (and costs) of personal assistance required per week.
Agree and Freedman 2000(30)	Retrospective analysis of data from a cross-sectional survey	Cane, walker, wheelchair, crutch	Data from the Disability Supplement to the 1994-1995 National Health Interview Phase 2 Survey were analyzed	Community-dwelling older Americans (total number not reported, ages not reported)	Use of assistive devices varies tremendously by activity. Over 60% of individuals with difficulty in walking, going outside, or toileting use assistive technology. In contrast, less than 10% of individuals with difficulty in eating or dressing use assistive technology. For all activities, individuals are more likely to use assistive devices if they also have access to personal assistance. Individuals using wheelchairs are more likely to also use personal assistance than individuals using walkers or canes.
Agree 1999(31)	Retrospective analysis of data from a cohort study	Cane, walker, wheelchair,	Data from the first wave of the Survey of Asset and Health Dynamics of the Oldest Old (1993) was analyzed	1,509 persons aged 70 and older who report some limitations in performing ADLs	Individuals who only use assistive devices report less residual difficulty with mobility than those who use personal assistance alone or in addition to assistive devices.

Study	Study design	MAD	Methods	Patient population	Conclusions
Mann et. al. 1999(32)	Randomized controlled trial	Cane, walker, wheelchair,	Patients were randomized to control group or to an intensive intervention group. Patients in the intensive intervention group were evaluated and given assistive technology devices (including wheelchairs) as needed	104 frail elderly community dwelling individuals	Patients in the intervention group received an average of 14.2 assistive devices from the study; patients in the control group obtained an average of 1.9 assistive devices from other sources. Over the 18 month follow-up period, functional capacity declined for both groups. However, there was significantly more decline in function for the control group. The control group required significantly more expenditures for health care. There were 11 serious falls in the control group and only 4 serious falls in the intervention group.
Verbrugge et. al. 1997(33)	Retrospective analysis of data from a cross-sectional survey	not specified	Data from the First National Health and Nutrition Examination Survey Epidemiologic Follow-up Study conducted 1982 to 1987 were analyzed	14,407 persons aged 25 to 74	Personal assistance is the principle type of assistance used with upper-extremity and body transfer tasks. Equipment only is the principle type of assistance used with lower-extremity tasks. Assistance (personal and/or equipment) completely resolves difficulty in performing ADLs for only 25% of affected persons.

ADL = Activities of Daily Living
 CHART = Craig Handicap Assessment and Reporting Technique
 FIM = Functional Independence Measure
 FSI = Functional Status Index
 IADL = Instrumental Activities of Daily Living
 OARS = Older Americans Research and Services Center Instrument