Johnson & Johnson

KATHLEEN A. BUTO
VICE PRESIDENT
HEALTH POLICY
GOVERNMENT AFFAIRS & POLICY

1350 EYE (I) STREET NW
WASHINGTON, DC 20005-3305
(202) 589-1000
FAX: (202) 589-1001
kbuto@corus.jnj.com

September 2, 2005

Mark McClellan, MD, PhD.
Administrator
c/o Steve Phurrough, MD
Director, Coverage and Analysis Group
Centers for Medicare and Medicaid Services
7500 Security Blvd. (Mailstop C1-09-06)
Baltimore, MD 21244

Re: **Formal Request for a Medicare National Coverage Determination for the INDEPENDENCE® 4000 iBOT™ Mobility System**

Dear Dr. McClellan:

Attached please find an electronic copy of a Formal Request for a Medicare National Coverage Determination for the INDEPENDENCE® 4000 iBOT™ Mobility System submitted by Independence Technology, LLC, a Johnson & Johnson company. We are also sending hard copies of this request under separate cover.

We are submitting this NCD request under Track No. 1 of the Revised Process for Making Medicare Coverage Decisions, 68 Fed Reg. 55, 634 (Sept. 26, 2003).

This NCD request is lengthy, complex, and seeks coverage of a breakthrough technology for people with mobility disabilities. The iBOT™ Mobility System has the potential to dramatically improve net health outcomes and the quality of life for a select group of Medicare beneficiaries, particularly those who require comprehensive functionality and can take maximum advantage of the device.

In order to ensure that CMS has a full understanding of our request and that we are given an opportunity to answer any questions that CMS may have, we hereby request a meeting with you to discuss our submission. I will follow up with your staff to arrange a convenient date and time and look forward to discussing this issue with you in depth. Thank you in advance for your consideration.

Sincerely,

Kathy Buto

Kathy Buto
Vice President, Health Policy

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INDEPENDENCE TECHNOLOGY
a Johnson & Johnson company

FORMAL REQUEST FOR A MEDICARE NATIONAL COVERAGE DETERMINATION

INDEPENDENCE® iBOT™ 4000 Mobility System: An Interactive Balancing Mobility System

Submitted by
Independence Technology, LLC
a Johnson & Johnson Company

September 2, 2005

Independence Technology, L.L.C.
45 Technology Drive
P.O. Box 4917
Warren, NJ 07059-4917
Tel: 908.412.2200
Fax: 908.412.2205

CONTACT INFORMATION

Questions and correspondence regarding this request should be directed to:

Gregg Howard
Vice President, Sales and Reimbursement
Independence Technology, LLC
45 Technology Drive
Warren NJ 07059-4917
Phone: (908) 412-2210
Fax: (908) 412-2205
GHoward@indus.jnj.com

TABLE OF CONTENTS

I. EXECUTIVE SUMMARY **4**

II. STATEMENT OF REQUEST **7**

III. BACKGROUND: FRAMEWORK FOR COVERAGE **8**
- A. Breakthrough Technology 8
- B. Coverage Considerations 9
- C. Context for Coverage by CMS 11

IV. PRODUCT DESCRIPTION **14**
- A. FDA Approved Indications for Use 14
- B. The Clinical Underpinning for Coverage of the iBOT™ Mobility System 15
- C. The Unique Nature of the iBOT™ Mobility System 16
- D. Technical Description of the INDEPENDENCE® iBOT™ 4000 Mobility System 17
- E. Functional Description of the iBOT™ Mobility System 19
  - (i) Negotiating Rough Surfaces and Extending Reach; 4-Wheel Function 21
  - (ii) Restoration of Balance/Maneuvering in Tight Spaces: Balance Function 21
  - (iii) Ascending and Descending Stairs: Stair Function 22
  - (iv) Maneuvering to Facilitate Transfers: Remote Function 23
  - (v) Power Locomotion from "Point A to Point B": Standard Function 23
- F. Unique Business Process 23
  - (i) Screening, Assessment, Prescription and Training Processes 23
  - (ii) Manufacturing and Customization 24
  - (iii) Delivery Training and Driver Testing 24
  - (iv) Distribution of the iBOT™ Mobility System 24
  - (v) Service and Maintenance: Comprehensive Service and Warranty 24
- G. Estimate of Demand for the iBOT™ Mobility System 25
  - (i) Impact of Age on the Demand Estimate 25
  - (ii) "Intent to Purchase" Data 26
- H. How Other Payers are Addressing Coverage of the iBOT™ Mobility System 27

V. BENEFIT AND COVERAGE RATIONALE **29**
- A. Benefit Category Recommendation 29
- B. How the iBOT™ Mobility System-IBMS-Meets the 4-Prong Definition of DME 29
  - (i) Durability 30
  - (ii) Medical Equipment 30
  - (iii) Appropriate for Use in the Home 31
- C. The iBOT™ Mobility System's Unique Functions are Covered DME Benefits 33
  - (i) Standard Function 34
  - (ii) Stair Climbing 34
  - (iv) Seat Elevation 38
- D. Establishing that the iBOT™ Mobility System is Reasonable and Necessary 40
  - (i) The iBOT™ Mobility System Meets the Standard of Medical Necessity 41

(ii) Assessing the Reasonableness of the iBOT™ Mobility System: Is the Benefit Worth the Expense? 43

VI. GENERAL INTENDED USE AND PURPOSE OF USE SPECIFIC TO MEDICARE BENEFICIARIES 49

A. Intended Use Specific to Medicare Beneficiaries 49
(i) Balancing the Benefit with the Need: A Look at Specific Patient Populations 49
(ii) Summary of the Clinical Studies' Findings 50
(iii) Congressionally Mandated Pilot Study 51
(iv) Power Wheelchair Users 51
(v) Manual Wheelchair Users: Imminent Risk of Secondary Injury 52
(vi) Manual Wheelchair Users: The "Wheelie" Standard 54

B. Purpose of Use – Ensuring Appropriate Access 55

C. Consistency Between the New NCD for Mobility Assistance Equipment and Coverage of the iBOT™ Mobility System 56
(i) Separate Coverage Criteria are Required for the iBOT™ Mobility System 56
(ii) The Coverage Determination Process for the iBOT™ Mobility System 57

VII. DISCUSSION OF EVIDENCE 60

A. Compilation of Evidence 60
(i) Primary Inclusion Criteria 61
(ii) Primary Exclusion Criteria 61
(iii) Function Specific Exclusion Criteria 61
(iv) Demographics 62
(v) Utilization Data 63
(vi) Safety Data 63
(vii) Effectiveness Data 64
(viii) Mechanical Failures, Computerized Alerts and Technical Difficulties 65
(ix) Computerized Alert and Failure Identification Data 65
(x) Mechanical/Operational Difficulties 66

VIII. CONCLUSION 67

BIBLIOGRAPHY

APPENDICES

I. EXECUTIVE SUMMARY

The INDEPENDENCE® iBOT™ 4000 Mobility System ("iBOT™ Mobility System") is a new type of mobility device that represents a genuine breakthrough in mobility technology for people who have long term mobility impairments. While virtually every manual wheelchair, power wheelchair, and power operated vehicle ("POV" or "scooter") on the market today confines the user to moving on relatively flat, smooth surfaces from point A to point B, the iBOT™ Mobility System offers users a full complement of functionality that is not available in any other mobility device. By permitting the user to negotiate variable surfaces, climb curbs and stairs, and "balance" at a standing eye-level position (whether at rest or in motion), the iBOT™ Mobility System virtually neutralizes access barriers in the home as well as the community. As such, the iBOT™ Mobility System addresses a full array of medical and functional needs for a subset of Medicare beneficiaries with long term mobility impairments whose functional status is severely compromised by the limitations of existing mobility technology.

As the Centers for Medicare and Medicaid Services ("CMS") reviews this National Coverage Determination ("NCD") request in depth, we would like to stress the following points:

- This NCD request will challenge CMS in at least two respects: (1) the iBOT™ Mobility System is a breakthrough technology that does not easily mesh with conventional assumptions and expectations of mobility devices and the functional needs of beneficiaries; and (2) although the device uses battery power to perform its functions, the clinical data suggest that the group of beneficiaries who could most benefit from the device consist of a subset of both existing power and manual wheelchair users.

- This NCD request asks CMS to establish Medicare coverage for a new type of durable medical equipment that we refer to as "Interactive Balancing Mobility Systems," of which the iBOT™ Mobility System is the first to come to market. (Creating coverage for a new type of Durable Medical Equipment ("DME") with distinct HCPCS coding will also give CMS the ability to use the capped rental method of payment for the device.)

- The iBOT™ Mobility System is a revolutionary mobility device with breakthrough technology. The device includes an integrated combination of six solid-state gyroscopes, three tilt sensors, and three computer processor systems that is customized to the user's size, weight and center of gravity. This is known as the iBALANCE™ Technology. The iBOT™ Mobility System has five operating functions: Standard; Four-Wheel; Balance; Stair; and Remote.

- The INDEPENDENCE® 3000 iBOT™ Mobility System was approved by the FDA on August 13, 2003 under an expedited Pre Market Approval (PMA) process. On March 14, 2005, the FDA approved the generational changes of the iBOT™ 4000 Mobility System. (See, Appendix A.) Unlike previous mobility devices that have been cleared through the less rigorous 510(k) process, approval of the iBOT™ Mobility System required the completion of clinical studies and device testing designed in cooperation with the FDA in order to establish safety and effectiveness. Expedited review is generally reserved for

devices that are considered to potentially offer a clinically meaningful benefit compared to the existing alternatives or when a new medical device promises to provide revolutionary or non-incremental advantage over currently available alternative modalities.

- Although the iBOT™ Mobility System offers users similar functionality to that of prosthetic limbs (See, Chart under Section V, A), it squarely meets the four prongs of the definition of durable medical equipment, including the "in the home" requirement, and each of its integrated functions (e.g., Standard Function, Stair Function, 4-wheel Function, and Balance or "Standing" Function) are primarily medical in nature and, therefore, covered DME.

- CMS' recently-announced NCD for Mobility Assistance Equipment ("MAE") adopts a functional standard that relies on an algorithmic process to determine which type of mobility device is appropriate for each beneficiary. Coverage of the iBOT™ Mobility System is consistent with the new NCD for MAE in that the device will clearly improve performance of or participation in mobility-related activities of daily living ("MRADLs") such as toileting, feeding, dressing, grooming and bathing in customary locations in the patient's home.

- Independence Technology, LLC ("Independence Technology") recommends that CMS adopt a coverage policy for the iBOT™ Mobility System that only applies to beneficiaries whose typical environment does not support the use of a manual or power wheelchair or scooter/power operated vehicle ("POV"): In other words, in instances where traditional mobility devices are considered unusable.

- Independence Technology recommends that CMS adopt a coverage policy for the iBOT™ Mobility System that is patterned from and is consistent with the algorithmic process used under the NCD for MAE for a subset of high functioning power wheelchair users and low functioning manual wheelchair users, as described in Section VI, C.

- This NCD request demonstrates that the iBOT™ Mobility System is reasonable and necessary for a small subset of Medicare beneficiaries in that the device improves net health outcomes for Medicare beneficiaries with mobility disabilities. The iBOT™ Mobility System will make a meaningful contribution to the treatment of an illness or injury of specific beneficiaries and the expense of the device to the program is not clearly disproportionate to the therapeutic benefits provided by the device.

- The extensive functionality that the iBOT™ Mobility System offers beneficiaries is not a "convenience" or "luxury." For Medicare beneficiaries with long term mobility impairments whose typical environment does not support the use of traditional mobility technology, there is no less costly, alternative pattern of care available.

- Recognizing the significant benefits that this revolutionary technology offers people with mobility disabilities, other public payers—including several state Medicaid programs and the Veterans Administration—have led the development of alternative coverage criteria

specifically designed to be relevant to the iBOT™ Mobility System. (See, Appendices I and J.) The Veterans Administration ("VA") has purchased eleven (11) iBOT™ Mobility Systems to assess beneficiary reaction. On March 1, 2005, the iBOT™ Mobility System was added to the Federal Supply Schedule. On March 22, 2005 the agency released its Clinical Practice Recommendation for the iBOT™ Mobility System. This document includes the coverage criteria and prescription protocol for the device.

- In arguing for coverage of a number of the iBOT™ Mobility System's unique functions, this NCD makes the case that current CMS coverage policy tends to inappropriately place greater value on improvement of functions (e.g., stair climbing, etc.) in ambulatory or potentially ambulatory patients and tends to undervalue achievement of these same functions in non-ambulatory patients.

- Independence Technology has created a unique business process that relies on functional assessments by independent, trained clinicians and a direct-to-consumer distribution model in order to accurately identify those beneficiaries who require it and will benefit most from the device. In this manner, Independence Technology (and CMS) will have an effective method to closely monitor utilization and assure its medical appropriateness.

- Development of a new type of DME coverage and coding for the iBOT™ Mobility System will enable CMS to develop specific patient selection criteria and documentation requirements for the device. (It will also permit CMS to consider using a capped rental payment methodology.) Independence Technology's recommended coverage criteria for the iBOT™ Mobility System derive from its clinical studies and FDA labeling requirements, detailed herein.

- Independence Technology recommends that the Medicare criteria for the iBOT™ Mobility System permit coverage for a small subset of high-functioning power wheelchair users, low-functioning manual wheelchair users, and manual wheelchair users at imminent risk of upper extremity injury secondary to manual wheelchair use, all of whom have a "typical environment" that does not support the use of traditional mobility devices.

- In a very real way, the iBOT™ Mobility System can be viewed as the embodiment of the New Freedom Initiative which seeks to create federal policies that break down barriers to community living for people with disabilities. The importance of securing a favorable coverage determination of the iBOT™ Mobility System for a small subset of Medicare beneficiaries who can maximize its functions cannot be overstated.

II. STATEMENT OF REQUEST

Independence Technology requests that CMS develop a National Coverage Determination ("NCD") providing for coverage of the iBOT™ Mobility System under the DME benefit and under the generic term "Interactive Balancing Mobility Systems." CMS should then set forth the specific requirements and conditions, including patient selection criteria, under which such coverage will be available to Medicare beneficiaries.

As the manufacturer of the INDEPENDENCE® iBOT™ 4000 Mobility System, Independence Technology is submitting this request for consideration under Track #1 as set forth in the Revised Process for Making Medicare Coverage Decisions.[1]

[1] 68 Fed. Reg. 55,634 (Sept. 26, 2003).

III. BACKGROUND: FRAMEWORK FOR COVERAGE

A. Breakthrough Technology

There have been many advances in mobility device technology throughout the past several decades as wheelchair designers and manufacturers have introduced battery power to manual devices, lightweight materials to standard wheelchairs and myriad accessories and wheelchair designs. These enhancements have significantly improved the function and quality of life of people with mobility impairments who rely on wheeled mobility. But all of these technological advancements have been limited to improving the basic ability of a mobility device to provide simple locomotion for its user. Virtually every manual wheelchair, power wheelchair, and power operated vehicle ("POV" or "scooter") on the market today confines the user to moving on relatively flat, smooth surfaces from point A to point B in the most efficient manner possible based on existing technology. But the world of the mobility device user is anything but flat and smooth, both inside the home and outside in the community environment.

Landmark federal and state laws have been enacted to attempt to make the manmade environment accessible to people in mobility devices; to, in effect, "level the playing field" for people with mobility disabilities. These laws have had moderate success in prompting the installation of "curb cuts" into sidewalks and ramps on buildings, but the problem of inaccessibility for people with mobility disabilities runs far deeper than an occasional curb cut and wheelchair ramp.

Until the introduction of the INDEPENDENCE® iBOT™ 4000 Mobility System—the first Interactive Balancing Mobility System ("IBMS")—little progress had been made in designing a mobility device that could virtually neutralize both the man-made and natural environments both inside and outside the home while providing unprecedented levels of functionality to users. As this National Coverage Determination ("NCD") request will establish, the iBOT™ Mobility System is such a device and is a breakthrough technology, one that currently has no equal in the mobility device marketplace.

We are *not* asserting that the iBOT™ Mobility System is the "best" power wheelchair on the market today. We *are* asserting that the iBOT™ Mobility System is not a power wheelchair at all. While it clearly meets the Medicare definition of durable medical equipment and may look like a power wheelchair to the casual observer, the iBOT™ Mobility System shares many characteristics with prosthetic devices and represents a new generation of mobility device that functions inherently differently than any power mobility device currently available. ***The enhanced functions it offers people with mobility impairments are embedded in the technology of the operating system and are interdependent upon one another.*** It represents a quantum leap from the technology used in traditional power wheelchairs and, therefore, should not be viewed as a series of "add-on" functions to a traditional power wheelchair.

Informal discussions with CMS to date have raised the question of whether these unique features are somehow severable from the remainder of the device and not "primarily medical in nature," one of the requirements for coverage of DME. As such, these features are viewed as "self-help"

devices or "environmental enhancing mechanisms" that do not qualify for coverage as DME. This view is contradicted by the fact that the Food and Drug Administration ("FDA") considers the iBOT™ Mobility System to be a Class III medical device, requiring a physician's prescription not only for Medicare reimbursement purposes, but even to be permitted to purchase the device. In contrast, all wheelchairs, stair elevators, and other such devices are considered Class II medical devices by the FDA, a sister agency to CMS.

B. Coverage Considerations

We recommend that CMS establish coverage for a new type of DME device, what we refer to as an "Interactive Balancing Mobility System," represented by the iBOT™ Mobility System. The development of specific coverage criteria will also be required in order to ensure that the iBOT™ Mobility System is provided only to those beneficiaries who can take maximum advantage of its enhanced functionality and require it in order to perform or participate in MRADLs in environments that are not supportive of traditional mobility devices. The iBOT™ Mobility System is clearly not for every individual with a mobility impairment. In fact, we envision a relatively small subset of Medicare beneficiaries with long term mobility disabilities that would ultimately receive the device. We look forward to working with CMS throughout the NCD process to arrive at a reasonable standard for coverage that meets the legitimate needs of beneficiaries while preserving precious Medicare resources.

In addition to over 40 million aged beneficiaries, Medicare covers over 6.0 million disabled beneficiaries below the age of 65.[2] Recent fraudulent activity that the Medicare program has experienced in the power wheelchair benefit does not diminish the need of specific beneficiaries for better access to highly functional mobility technologies. The Medicare program is, therefore, in a unique position to set the standard for access to wheeled mobility and, for that matter, assistive devices generally.

Access barriers to a wide range of assistive devices have been documented to result in physical consequences of beneficiaries, such as a general deterioration in health and a risk of secondary injuries, as well as strained relationships with family, friends, and colleagues, financial strain, decreased independence, and limitations in social participation.[3] Wheelchairs are used to enhance function, to improve independence, and to enable a person to successfully live at home and in the community.[4,5] On the other hand, a wheelchair may be perceived as negatively impacting a person's life if it does not enable him/her to participate fully in social and community activities.[6] Moreover, personal adverse effects associated with being homebound

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[2] Centers for Medicare and Medicaid Services, Office of Research, Development and Information; July 1, 2002.

[3] M.T. Neri & T. Kroll, *Understanding the Consequences of Access Barriers to Health Care: Experiences of Adults with Disabilities*, 25(2) DISABILITY AND REHABILITATION 85-96 (2003).

[4] Scherer M, Cushman L. Measuring subjective quality of life following spinal cord injury: a validation study of assistive technology device predisposition assessment. Disabil Rehabil 201;23:387-93.

[5] Smith RO. Measuring the outcomes of assistive technology: challenge and innovation. Assist Technol 1996;8:71-81.

[6] Mann WC, Hurren D, Charvat B. Problems with wheelchair experienced by frail elders. Technol Disabil 1996;5:101-11.

include dysthymia, reduced social and leisure activities, lower life satisfaction, greater use of home healthcare services and malnutrition.[7, 8, 9] One study found, as expected,[10, 11] people reporting mobility difficulties were more likely than others to be impoverished, poorly educated and unable to work. They were also more likely to live alone, even though they reported lesser ability to perform routine daily activities, such as preparing meals. The combined effects of poverty and inability to perform daily tasks raise fundamental questions about quality of life.[12]

This NCD request is being submitted shortly after a comprehensive review by the Medicare program of its coverage policies for mobility devices. On December 15, 2004, CMS announced its intention to develop a new National Coverage Determination for mobility devices based on functional criteria. On May 5, 2005, CMS issued Transmittal 37, an NCD for Mobility Assistive Equipment ("MAE") including canes, crutches, walkers, manual wheelchairs, power wheelchairs, and scooters. However, CMS explicitly stated that this was not an exclusive list of MAE. In that NCD, CMS found that the evidence is adequate to determine that MAE is reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to impair their participation in mobility-related activities of daily living in customary locations *in the home.*

The "in the home" criteria, which limits coverage of wheelchairs to those that are reasonable and necessary "in the patient's home" is under serious attack by interest groups and beneficiary organizations. In addition, a number of influential organizations such as the AARP and the National Academy of Social Insurance have called for reform in this area in order to better meet the assistive device needs of Medicare beneficiaries.[13]

The Bush Administration has signaled its interest in advancing this issue through the New Freedom Initiative's ("NFI") emphasis on "assistive technology" for people with disabilities. In fact, one of the issues that the Department of Health and Human Services committed to

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[7] Farquhar M, Bowling A. Elderly housebound: Changes over time. Nursing Standard 1993;8:26-31.

[8] Branch LG, Wetle TT, Scherr PA, et al. A prospective study of incident comprehensive medical home care use among the elderly. Am J Public Health 1988;78:255-9.

[9] Bruce ML, McNamara R. Psychiatric status among the homebound elderly: An epidemiologic perspective. J Am Geriatr Soc 1992;40:561-6.

[10] Kovar MG, Weeks JD, Forbes WF. Disability among older people: United States and Canada. Vital Health Stat 5. 1995;(8):1-82.

[11] DeJong G, Batavia AI, Griss R. America's neglected health minority: working-age persons with disabilities. Milbank Q. 1989;67 Suppl 2 Pt 2:311-51.

[12] Bassuk SS, Glass TA, Berkman LF. Social disengagement and incident cognitive decline in community-dwelling elderly patients. Ann Intern Med. 1999;131:165-73.

[13] "Durable medical equipment ("DME") is an instance where Medicare policies fall short of helping beneficiaries to maximize function and quality of life. DME coverage policy requires that the equipment be used primarily in the home. This policy is an obstacle, particularly for younger, disabled beneficiaries who would like to try to work outside the home, as well as those who would prefer to lessen their dependence on others by living more independently. For example, beneficiaries who have trouble walking may need the use of a motorized scooter outside of the home but have difficulty getting it approved because of the 'primarily in the home' requirement." *Medicare in the 21st Century: Building a Better Chronic Care System*, NATIONAL ACADEMY OF SOCIAL INSURANCE 19 (Jan. 2003), *at* http://www.nasi.org/usr_doc/Chronic_Care_Report.pdf.

addressing under the NFI in 2001 was the "in the home" restriction on durable medical equipment under the Medicare program. To date, however, significant progress has not been achieved in modifying this limitation on durable medical equipment for Medicare beneficiaries with mobility impairments despite the fact that nearly 100 members of Congress recently wrote to HHS Secretary Leavitt expressing concerns with CMS' restrictive interpretation of the "in the home" rule.

The Administration's focus on mobility devices was, in part, prompted by implementation of the Olmstead Supreme Court case (Olmstead v. L.C., 527 U.S. 581, 600, 119 S. Ct. 2176 (1999)) which requires federal programs to eliminate barriers to the community for people with disabilities. It was also prompted by the Ticket to Work and Work Incentives Act (Pub. Law 106-170) which extends Medicare coverage for SSDI recipients who return to the workforce and leave the disability rolls. Unfortunately, Medicare's "in the home" criterion appears to be in conflict with the Ticket to Work law's intent to provide incentives for people with disabilities to leave their homes and re-enter the workforce.

C. Context for Coverage by CMS

The Institute of Medicine's ("IOM") Committee on Assessing Rehabilitation Science and Engineering has also addressed this issue by publishing, Enabling America in 1997.[14] The IOM stated that people with disabling conditions have increased needs in order to reintegrate into their environment. The process of "enabling the disabled" attempts to either restore function in the individual or expand access to the environment. Both of these approaches are difficult for Medicare to accomplish given its current interpretation of the "in the home" criterion. But CMS clearly has the authority to make significant progress in at least two other areas that would significantly improve the Medicare mobility device benefit:

(1) greater, more consistent recognition of *functional improvement* in the medical necessity determination, and

(2) greater, more consistent recognition of the value of attempting to *reduce injuries secondary* to prolonged manual wheelchair use.

- Functional Improvement: A Component of the Medical Necessity Determination: The restoration of physical function is the purpose for a wide array of medical devices and procedures currently in use and routinely covered by Medicare. Functionality is integral to health status and restoration of function of people with physical disabilities is what defines the field of medical rehabilitation. Medicare has clearly recognized functional improvement in the medical necessity determination for a variety of assistive devices. For example, under Medicare's prosthetic device (artificial limb) benefit, higher functioning, technologically-advanced prosthetic components are covered for beneficiaries with higher functional potential, as assessed by the physician in consultation with the treating prosthetist.

[14] ENABLING AMERICA: ASSESSING THE ROLE OF REHABILITATION SCIENCE AND ENGINEERING (N. Brandt & A. Pope, eds., Committee on Assessing Rehabilitation Science and Engineering, Institute of Medicine 1997).

Similarly, Medicare covers lightweight and ultra-lightweight wheelchairs to enhance the functional capacity of people with mobility impairments who have difficulty self-propelling heavier wheelchairs. The level of functional capacity of the individual should be measured as it relates to the whole person. In the mobility device area, it is the potential for functional improvement that establishes whether a particular device "adds value" to Medicare beneficiaries with disabilities. Recognition of functional improvement, therefore, should play an explicit and expanded role in mobility device coverage policy. To its credit, CMS has recently acknowledged the importance of functional improvement through the adoption of the NCD for MAE, albeit the improvement in function is confined to the beneficiaries' home environment.

The iBOT™ Mobility System introduces functions to Medicare beneficiaries with mobility impairments that have never before been possible, particularly in a single, integrated device. These functions include better performance of daily life activities including both "horizontal ambulation" (i.e., going from point A to part B) as well as "vertical ambulation" (i.e., going up and down stairs and other inclines/declines in the home). These functions also include other activities that involve balance, extension and reach. It is critical that CMS considers these improvements in function as relevant factors in meeting the medical necessity standard. In a real sense, the wheelchair is an extension of the user's body. Therefore, it is critical that any mobility device must match the user's current expectations, preferences, physical needs, and functional requirements based on his/her interactions with the environment.[15]

- Minimizing Secondary Injuries and Conditions: Many Medicare beneficiaries develop injuries or conditions secondary to long term manual wheelchair use. Significant clinical evidence establishes that long term wheelchair users experience repetitive motion injuries in the upper extremities resulting in mild to severe stress injuries to the shoulder, elbow, wrist and hand. These injuries are predictable, avoidable, and costly to address medically once they manifest themselves.[16] (See, Section VI, A (v), *infra,* for clinical references.) Current Medicare wheelchair coverage policy, however, does little to address the "conservation" treatment options (non-surgical) of this significant problem in the wheelchair user population.

  In the case of the iBOT™ Mobility System, the clinical studies strongly indicate that the enhanced functions are not only medically necessary for some current power wheelchair users, but also reasonable and necessary for a portion of the manual wheelchair population. This portion consists of low functioning manual users and those at imminent risk of upper extremity impairment. These segments of the manual wheelchair

[15] Batavia M, Batavia A, Friendmans R. Changing chairs: anticipating problems in prescribing wheelchairs. Disabil Rehabil 2001;23:539-48.

[16] Surgical intervention to treat secondary injuries such as these are often far more costly than the immediate surgical and physician fees. These types of cases often require lengthy inpatient rehabilitation stays due to the inability of the disabled patient to live independently during the healing process, resulting in overall treatment costs that often extend into tens of thousands of dollars for each case.

population could obtain tremendous benefits from the device, without having to encounter the mobility limitations of current power wheelchair technology.

- Cost Considerations of the iBOT™ Mobility System: The significant advances in function that the iBOT™ Mobility System brings to Medicare beneficiaries with mobility disabilities are reflected in the cost of the device in comparison to other mobility devices currently covered by the program. After years of development of this revolutionary technology, the iBOT™ Mobility System's cost is more akin to computerized prosthetic devices or other medical/surgical interventions than to many traditional power wheelchairs, for instance. To a specific set of Medicare beneficiaries, the iBOT™ Mobility System's enhanced functionality will be well worth the cost. It is the purpose of this NCD to demonstrate this value proposition and attempt to define which Medicare beneficiaries require and would most benefit from this new technology.

  Interactive Balancing Mobility Systems should *not* be considered medically necessary by the Medicare program when the device is beneficial primarily in allowing the user to perform leisure or recreational activities or when the device is used exclusively outside of the home. However, patients for whom the device is medically necessary will benefit from the enhanced functional capabilities and quality of life benefits that this device provides across all types of activities of daily living in home, work and community settings.

  The mobility device market is now at a stage where devices exist that are capable of providing unprecedented levels of function to select individuals with mobility disabilities. The Medicare program has made great strides in recent years in covering new drugs and innovative medical and surgical technologies, including highly sophisticated, computerized prosthetic limbs. Despite their cost, the full range of these items and services has often been of tremendous value to Medicare beneficiaries, prolonging life as well as improving health and the quality of life.

  This NCD request for coverage of the IBMS, represented by the iBOT™ Mobility System, presents CMS with an opportunity to demonstrate that the Medicare program's interest in providing beneficiaries with access to breakthrough technologies is not limited to acute care settings or ambulatory patients capable of full restoration of health and function. A positive coverage determination for the iBOT™ Mobility System in this instance will demonstrate that nonambulatory Medicare beneficiaries—whose functionality can be almost entirely restored through an assistive device—are just as valuable and worthy of the investment of public resources.

IV. PRODUCT DESCRIPTION

The iBOT™ Mobility System is a revolutionary mobility device with breakthrough technology. The standard definition of a powered wheelchair is a battery-operated device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position. A power wheelchair simply takes a person from point A to point B. While the iBOT™ Mobility System meets all of the requirements of this classification (e.g., battery operated, has wheels and is intended for use as described above), the classification does not include any of the advanced mobility functions that are integrated into this unique device. Clearly, when the current DME benefit was conceived, it was not envisioned that a class of mobility devices would exist that provides dynamically stabilized functions that enable functional restoration comparable to that of a lower limb prosthesis. (See, chart under Section V, A.) The interdependent, function-restoring capabilities of the iBOT™ Mobility System are unquestionably above and beyond classification as a standard power wheelchair.

A. FDA Approved Indications for Use

The INDEPENDENCE® 3000 iBOT™ Mobility System was approved by the FDA on August 13, 2003 under an expedited Pre Market Approval (PMA) process. On March 14, 2005, the FDA approved the generational changes of the iBOT™ 4000 Mobility System. (See, Appendix A.) Unlike previous mobility devices that have been cleared through the less rigorous 510(k) process, approval of the iBOT™ Mobility System required the completion of clinical studies and device testing designed in cooperation with the FDA in order to establish safety and effectiveness. Expedited review is generally reserved for devices that are considered to potentially offer a clinically meaningful benefit compared to the existing alternatives or when a new medical device promises to provide revolutionary or non-incremental advantage over currently available alternative modalities.

Based on information submitted by Independence Technology, the FDA determined that the iBOT™ Mobility System "offer[s] significant advantages over existing approved alternatives" and, as such, granted expedited review for the device. This criterion applies to devices which the FDA believes have the potential to provide for clinically important earlier diagnosis or offer important advances in safety and/or effectiveness over existing alternatives. [17]

The iBOT™ Mobility System is indicated only for select individuals who, at a minimum, have long term or permanent mobility impairments and are capable of safely operating the device. The iBOT™ Mobility System must be ordered by a treating physician and will require a prescription, not merely for purposes of payment by third parties, but in order for potential users to have access to the device. Specially trained clinicians[18] conduct an assessment with potential users to determine if they are appropriate for the device. In addition to a physician's

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[17] FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY AND FDA STAFF: EXPEDITED REVIEW OF PREMARKET SUBMISSIONS FOR DEVICES (2003), *at* http://www.fda.gov/cdrh/mdufma/guidance/108.pdf.

[18] Independence Technology provides a comprehensive training program to clinicians who conduct the assessments and training for the iBOT™ Mobility System. The majority of clinicians are occupational therapists or physical therapists, although physiatrists may also be trained. All of these clinicians are independent from the company.

prescription, patients must complete a comprehensive training program that instructs them how to safely operate the multiple functions of the device.

The FDA imposes additional restrictions specific to the iBOT™ Mobility System. These restrictions limit use to those individuals who meet the following criteria:

- The patient weighs no more than 250 pounds. The current design of the iBOT™ Mobility System has a total weight capacity of 250 pounds.

- The patient is able to bend his or her knees and hips such that the patient's back and feet fit on standard rests. As currently designed, the iBOT™ Mobility System can only accommodate users who use standard footrests (for people with an amputation(s) this does not apply). As currently designed, the iBOT™ Mobility System backrest does not recline to accommodate users who cannot sit in a standard wheelchair.

- The patient's current postural supports are compatible/comparable with the postural supports on the iBOT™ Mobility System.

- The patient meets driver licensing criteria established in 1996 by the Epilepsy Foundation of America.

- The patient does not currently require use of a tilt or recline seating system as a mechanical method of pressure relief.

- The patient does not require mechanical ventilation.

- The patient has sufficient use of at least one upper extremity.

Additionally, the iBOT™ Mobility System is currently available in seat sizes 16" and 18" wide. Users who experience a weight gain or loss of 20 pounds or more or whose functional capabilities have changed are instructed to consult with their clinician for reassessment and potential recalibration of the device's center of gravity.

Independence Technology is required to provide the FDA with four semi-annual reports summarizing product usage information from the device data logs, device failures and reported adverse events. Additionally, as part of the Pre-Market Approval requirements, the company will submit annual reports.

B. <u>The Clinical Underpinning for Coverage of the iBOT™ Mobility System</u>

The iBOT™ Mobility System represents a substantial leap forward in mobility technology. Distinguished from wheelchairs and power operated vehicles (POVs), it is an all-in-one mobility device that virtually "neutralizes" the physical barriers of both natural and man-made environments. The user is able to overcome vertical and horizontal barriers, thereby "leveling the playing field." One's physical environment determines which tasks need to be performed

and can impact the individual's ability to live independently.[19, 20] Richards, et al.[21] reported that environmental access increases the likelihood that a person with spinal cord injury will engage in a variety of meaningful activities. The iBOT™ Mobility System was designed with this in mind. The device breaks new ground in terms of increased function for beneficiaries with mobility impairments in a way that has the real potential to change peoples' lives.

A number of clinical studies found, consistent with the NCD for MAE, that there are significant benefits to increasing a beneficiary's functionality. Hoenig, et al. found that environmental barriers were negatively related to medical and nonmedical visits, and mobility impairments (or lack thereof) predicted the frequency of medical and nonmedical visits as well. From a public health perspective, this finding indicates that effective treatment of mobility impairments could improve quality of life and access to care in this population. The results imply that, for mobility-impaired individuals, chronic conditions and functional limitations have countervailing effects on medical visits by increasing the need for care while decreasing the ability to visit providers.[22] Moreover, Mann, et al. referenced in the NCD for MAE found that, though there is decline in function in both people who use MAE, including wheelchairs, and those who do not, over time the MAE group has less of a decline.[23] Lindesay and Thompson found that homebound subjects were more likely to experience environmental constraints within the home (living on a second floor) or rental residence.[24] The findings show that environmental barriers within the home and near the home (e.g., steps) appear to impede participation in a diverse range of activities.

C. The Unique Nature of the iBOT™ Mobility System

A number of specialty mobility devices exist on the market today that permit the user to perform one or more functions listed below, but no other currently-available device exists that can perform all of the iBOT™ Mobility System's functions—even with the assistance of another person. Until the iBOT™ Mobility System was invented, beneficiaries had been limited in the level of functional restoration achievable by traditional DME mobility devices—manual wheelchairs, power wheelchairs and POVs. Conventional power devices, although useful for locomotion and propulsion, are generally unable to navigate barriers such as small rises, curbs, stairs and confined spaces. No wheelchair or POV restores basic physical functions such as reach, extension, and balance in a standing position.

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[19] Gray D, Gould M, Bickenbach JE. Environmental barriers and disability. J Architectural Plann Res 2003;20:29-37.

[20] Rogers J, Holm M. Task performance of older adults and low assistive technology devices. Int J Technol Aging 1991;4:93-106.

[21] Richards JS, Bombardier CH, Tate D, et al. Access to the environment and life satisfaction after spinal cord injury. Arch Phys Med Rehabil 1999;80:1501-6.

[22] Hoenig H, Landerman LR, Shipp KM, George LG. Activity restriction among wheelchair users. J Am Geriatr Soc 2003;51:1244-51.

[23] Mann WC, Ottenbacher KJ, Fraas L, Tomita M, Granger CV. Effectiveness of assistive technology and environmental interventions in maintaining independence and reducing home care costs for the frail elderly. A randomized controlled trial. Arch Fam Med 1999 May-Jun;8(3):210-7

[24] Lindesay J, Thompson C. Housebound elderly people. Definition, prevalence and characteristics. Int J Geriatr Psychiatry 1993;8:231-37.

The iBOT™ Mobility System is the first type of mobility device that offers dynamic stabilization (e.g., balance), enabling multiple mobility functions not previously available in a single device. This new type of device, what we refer to as "Interactive Balancing Mobility Systems" features the iBALANCE™ Technology. This new technology consists of an electronic balance system that is custom programmed and calibrated to allow it to constantly realign and customize itself to the unique movements of each user in real time. The iBALANCE™ Technology is an integrated combination of sensors, gyroscopes and software components that work together to mimic the principles of human balance to provide dynamic stabilization. Gyroscopes are complex motion sensors that help maintain balance. When the gyroscopes in the device sense movement, a signal is sent to the computer which processes the information and tells the motors how to adjust the wheels to maintain stability and balance.

As a result, the iBALANCE™ Technology maintains balance in the forward and backward direction. The IBMS analyzes and bi-directionally processes data hundreds of times per second, constantly realigning, adjusting, and responding to the unique—and immediate—movements of each individual user. The device interacts with the user to ensure a relatively level and stable ride regardless of the user's movements, functions of the device, or obstacles encountered. The iBALANCE™ Technology, however, does not electronically maintain side-to-side stability.

The iBALANCE™ Technology enables the IBMS to perform functions that are not offered by any single mobility device currently available, including manual wheelchairs, power wheelchairs, specialty wheelchairs and POVs. These unique features allow the beneficiary to:

- Achieve simple, battery-powered locomotion
- Negotiate carpet, rough surfaces or inclines/declines
- Traverse grass, sand, gravel, unpaved pathways and other uneven surfaces (e.g., eases entry into and out of home)
- Balance and reach to a "standing" level while in a sitting position for improved extension and interaction with others
- Achieve balance, stability and safety during locomotion, including at a standing height
- Maneuver in tight spaces
- Climb curbs, door thresholds, or ramps
- Climb steps or entire flights of stairs

These barriers and challenges constitute a comprehensive set of reasonable and necessary medical and functional needs for people who spend their lives using wheeled mobility. Because of these breakthrough capabilities, the current NCD for MAE must be amended in order to define reasonable and necessary coverage criteria for this new type of mobility device.

D. Technical Description of the INDEPENDENCE® iBOT™ 4000 Mobility System

The iBOT™ Mobility System is the first IBMS to be commercially available in the United States. This NCD request contains information specific to the iBOT™ Mobility System, but is

representative of the IBMS category in general. (See, Appendix B for pictures of the iBOT™ Mobility System in two different functions, Stair Function and Balance Function.)

- The iBOT™ Mobility System is one of the most thoroughly tested devices in the mobility device category. In addition to ISO and ANSI/RESNA standards testing, the iBOT™ Mobility System has been clinically tested by people with disabilities as part of the FDA approval process.

- The iBOT™ Mobility System is an integrated combination of mechanical, electronic, sensor, and software components that is customized to the user's size, weight and center of gravity. The iBALANCE™ Technology is comprised of six solid-state gyroscopes, three tilt sensors, and three computer processor systems.

- The iBOT™ Mobility System integrates this extensive technology with a cluster of two, interconnected, 12-inch wheels on each side of the device as well as two smaller caster wheels in the front of the device. The device automatically adjusts wheel and/or frame position in reaction to changes in pitch, wheel velocity, wheel position, seat height and other parameters based on a complex series of computerized sensors and software algorithms.

- The sensors and processors execute the control algorithms which are replicated three times in the system to provide triple redundant control processing for dynamically stabilized functions. In these functions, the device continuously and automatically adjusts to account for movement of the device and the user's center of gravity.

- Numerous safety precautions are programmed into the iBOT™ Mobility System. Aside from the redundant computer processors that serve as backup "safety" systems, the device uses visual and auditory signals on the User Control Panel to provide the user with caution signals, warning signals and other information about the product status.

- The iBOT™ Mobility System is powered by two, 67.2-volt rechargeable nickel-cadium (NiCad) batteries that can power the device all day on a single charge depending on usage. If one battery fails, the second battery is capable of providing enough power for the product to continue operating at full function. When recharging, batteries will reach 80% of full charge in 6 hours and 100% of full charge in 8 hours. Each battery weighs approximately 24 lbs. The batteries as well as a battery charger are included in the price of the device.

- One of the many unique features of the iBOT™ Mobility System is the detachable User Control Panel ("UCP") that features a joy-stick operated steering system that is proportional and directional. The UCP is integrated into the armrest of the seating system and may be detached to enable remote operation from up to 39 inches away when the user is not in the device. Incorporated into the UCP is an external computer connection for remote diagnostic purposes, software updates and technical support from Independence Technology. (See, Appendix C for a picture of the iBOT™ Mobility System's User Control Panel.)

- In addition to the software customization or calibration to the user's body size, weight and center of gravity, the iBOT™ Mobility System can be adjusted to the user's seating and

positioning needs by making adjustments to the swing-away footrest (height and angle), footplate (angle), calf strap, back rest (angle), armrest position, and seat position.

- To facilitate transfers into and out of the device, both the clothing guard and the armrest can be folded back to allow easy access. The toe guard can swing away to reduce obstructions and the footrest can be removed.

- The iBOT™ Mobility System has an electronic security system which prevents use by others for whom the device has not been prescribed and is a deterrent to theft.

E. Functional Description of the iBOT™ Mobility System

The iBOT™ Mobility System has five operating functions: Standard; Four-Wheel; Balance; Stair; and Remote. Four of the operating functions rely on the iBALANCE™ Technology: Four-Wheel, Balance, Stair and Remote. Each function uses the core technology in a slightly different way, as summarized in the following chart:

IBOT™ Functions	iBALANCE™ Technology	Surfaces	Obstacles	Max Incline	Min. Turn Radius	Max Speed	User Adjusted Seat Height	Seat Tilt
4-Wheel	Active	High door thresholds; Rough surfaces: grass, water up to three inches	5 in.	10°	29.9 in.	4.8 mph	at least 26.3 in.	N/A
Balance	Active	Flat, level surfaces (non-slippery) and ADA compliant ramps and inclines	1 in.	5°	30.6 in.	3.2 mph	at least 33 in.	N/A
Stair	Active	Flat sturdy stairs 5" – 8" height, 10" – 17" length	N/A	N/A	N/A	N/A	N/A	N/A
Remote (backrest folded forward)	Active	To move when unoccupied	1 in.	20°	31.6 in.	0.6 mph	N/A	N/A
Standard	Non-Active	Flat, level surfaces and ADA compliant ramps and inclines	1 in	5°	39.8 in.	6.8 mph	18 in	10°

SEAT ELEVATION: Seat Elevation is permitted during three of the five functions of the iBOT™ Mobility System: 4-Wheel Function, Balance Function, and Stair Function. Seat elevation is separate and distinct from the ability of the device to raise the seated user to standing-level height. This function is known as "Balance" function. The ability for users in the three functions to raise their seat height above the standard level significantly improves the ability to reach objects on shelves, maintain an eye-level position when conversing with others, access sinks and mirrors during personal grooming, access counters for food preparation, and access cook tops for improved safety and function in the home. The seat can also remain safely elevated while the device is being driven.

The ability to elevate one's seat has arguably become more relevant to the coverage determination process since publication of the NCD for MAE. The new NCD will consider the ability of different types of MAE to increase participation in and performance of "mobility related activities of daily living." This term is defined to include toileting, feeding, dressing, grooming and bathing, but this is not an exhaustive list. Other activities in the home setting may also be considered (e.g., cooking, laundry, housekeeping). Many of these activities will either be enhanced or will only be accomplishable with the use of an iBOT™ Mobility System, particularly when traditional mobility devices are unusable in a beneficiary's home due to access barriers.

(i) Negotiating Rough Surfaces and Extending Reach; 4-Wheel Function

4-Wheel Function provides the user with mobility and flexibility on a wide variety of surfaces. 4-Wheel Function enables users to negotiate in-home and community obstacles up to five inches high. This function eases entry into and out of the home (single step or curb), and enables the user to traverse high door thresholds or single steps between rooms. In 4-Wheel Function, the device also traverses inclines up to ten degrees and soft, uneven surfaces such as gravel, dirt, grass, and even water up to three inches deep. This function is obviously useful in community environments but it clearly holds implications for improving performance of or increasing participation in MRADLs in the home, as the examples above illustrate, particularly in homes that do not otherwise support traditional wheelchair use. In addition, the user-controlled seat height is 28 inches (31 inches for the automotive seat option). While in the 4-Wheel Function, the iBOT™ Mobility System has a minimum turning radius of 30 inches and a maximum forward speed of 4.8 miles per hour.

In 4-Wheel Function, the iBALANCE™ Technology, sensor data and user commands are processed so that the device reacts to changes in pitch caused by the changes in the surface encountered as well as other factors. The device uses both the wheel and "cluster" position to maintain stability. For example, if the user drives the device up a curb, the cluster will rotate (in reaction to the change in pitch) to maintain a level seat as the wheels drive forward. This same phenomena occurs when the device encounters an indoor or outdoor ramp or another type of obstacle such as a step between the kitchen and living room. In this manner, the stability of the user is enhanced even during a steep or abrupt ascent or descent. When the seat is elevated, the iBALANCE™ Technology enables the user to maintain stability when extending reach to perform various mobility related activities of daily living.

(ii) Restoration of Balance/Maneuvering in Tight Spaces: Balance Function

Balance Function provides mobility at an elevated or "standing" height. As the name suggests, in Balance Function, the iBOT™ Mobility System mimics human balance in that it operates on two points of contact with the ground. This is accomplished by the user selecting the Balance Function on the UCP and leaning back in the seat or pushing the joystick forward, which shifts the combined weight of the device and the user over the back two wheels (without, of course, tipping backward). The device reacts to this change to the center of gravity by transitioning the device upward and balancing on the two sets of wheels that have become vertically aligned. A

brake locks the clusters into this vertical arrangement but the two wheels move freely, reacting in real time to subtle changes in the user's center of gravity, resulting in the device balancing itself either in a stationary or moving position.

In Balance Function, the seat height can be lowered and raised to a maximum seat height of 34 inches (38 inches for the automotive seat option) to facilitate the reaching of objects on shelves or inside kitchen and medicine cabinets or having an "eye-level" conversation with a standing person. The Balance Function is appropriate for firm surfaces with an incline up to five degrees and obstacles up to one inch high. Balance function permits significant functional improvement in the ability to perform a variety of MRADLs, especially in home environments that do not support the use of traditional mobility devices.

(iii) Ascending and Descending Stairs: Stair Function

Stair Function enables the user to ascend or descend commonly encountered steps or stairs either with the help of an assistant or under the user's own power. Stair climbing is achieved by the rotation of the clusters—one wheel over another—one step at a time. This function uses a closed-loop control algorithm that uses pitch and sensor data to control the cluster motors, which in turn maintains the balance of the device while ascending or descending the stairs. The device automatically keeps the center of gravity of the device over the ground-contacting wheels. Negotiating stairs with the iBOT™ Mobility System is not dependent upon the strength of the user or assistant. Stair-climbing is solely accomplished through changes to the center of gravity of the user and the device. The device itself does the heavy lifting.

When a user leans either forward or backward (or an assistant helps lean the device for the user), the center of gravity shifts and the device reacts by automatically rotating the clusters in response. This, in turn, results in the device climbing up or down one stair at a time. The user climbs up and down a staircase facing down the stairs with the direction of the weight shift (lean) determining the direction of climbing (e.g., leaning forward to descend and backward to climb). The joystick automatically deactivates when the device is in Stair Function to prevent unintentional deflection of the joystick on the stairs. When a stairway landing area is reached, the user transitions into 4-Wheel Function and drives away from the stairs. The user/assistant is the input device during stair climbing as they control the rate of climbing and provide stability by holding the stair handrails (user) or the Assist Handle on the back of the seat (assistant).

The draft NCD for MAE referenced the need for "stair climbing" as an example of when a beneficiary's home environment may not be supportive of traditional wheeled mobility and, therefore, such wheeled mobility may not be reasonable and necessary. The final NCD for MAE is consistent with this concept in that question number 6 of the algorithmic process addresses whether a person's environment would render mobility equipment unusable in the beneficiary's home. The fact that a mobility device now exists that can overcome steps or stairs as a barrier to coverage of *any* mobility device is significant and seems to uniquely address this stage of the algorithmic process for coverage of MAE.

(iv) Maneuvering to Facilitate Transfers: Remote Function

Remote Function provides the user with a way to operate the iBOT™ Mobility System when not seated in it. Remote Function is useful for maneuvering the device for transfers, parking the device after a transfer, driving the device into a vehicle for transport and for other purposes. The User Control Panel may be removed from its mount on the armrest and operated via a five-foot length of retractable cable. Entry into Remote Function is only allowed when the seat is folded to prevent use of this function when a user is seated in the device. This is because the device was designed to have an empty seat in this function. Since the device does not have to keep a user stable during this function, it is able to traverse inclines up to 20 degrees. While this function is very useful for steep inclines, it is not appropriate for obstacles other than firm, even surfaces with no greater than one-inch obstructions.

(v) Power Locomotion from "Point A to Point B": Standard Function

In Standard Function, the iBOT™ Mobility System does not use the iBALANCE™ Technology. In this function, the mobility system behaves similar to a traditional power wheelchair. The seat is at the lowest available position in this function. The casters attached to the front of the base of the seat are in contact with the ground and the front set of the two sets of drive wheels are raised off the ground. The casters provide effective turning performance in this function. As with currently available power wheelchairs, the use of casters limits the surfaces and obstacles that can be negotiated. Standard Function is appropriate for relatively flat and firm surfaces (e.g., in the home, other indoor environments, sidewalks, and pavement) with up to a five degree incline and obstacles up to one inch.

As with all of the iBOT™ Mobility System's other functions, standard function assists individuals in performing MRADLs in the home. This is consistent with improvements of MRADLs permitted by standard power wheelchairs. However, the full complement of functions of the iBOT™ Mobility System, combined in one portable device, produce exponential gains in MRADLs for beneficiaries whose home environments do not support standard wheelchairs.

F. Unique Business Process

Independence Technology, the first Johnson & Johnson company to become a Medicare supplier, has developed a unique business process to provide the iBOT™ Mobility System to the most appropriate users of the device while maintaining accountability in the patient selection, distribution, and servicing processes.

(i) Screening, Assessment, Prescription and Training Processes

The Medicare program has historically considered the physician's prescription and the Certificate of Medical Necessity ("CMN") sufficient to establish that wheelchairs and POVs meet medical necessity criteria for a given patient, assuming that documentation in the patient's file supports the prescription and CMN. Prior to being prescribed an iBOT™ Mobility System, however, patients interested in the iBOT™ Mobility System who contact the Independence Customer

Service Center must first be screened using a pre-qualification survey to rule out any contra-indications.

Patients who successfully complete the pre-qualification survey must be assessed by an independent health care professional to evaluate whether they are an appropriate candidate for the iBOT™ Mobility System. If the consumer is determined to be a candidate for the device, he or she must also successfully complete a comprehensive six to eight hour driver training program. The health care professional performing the assessment is not an employee of Independence Technology and must be a licensed physiatrist, physical therapist, or occupational therapist.

(ii) Manufacturing and Customization

The iBOT™ Mobility System is manufactured and modified specifically to each user. An "order" to manufacture an iBOT™ Mobility System will be based on patient-specific medical and functional characteristics as determined by the physician's prescription and the clinician's functional evaluation. This process results in a device that is custom programmed based on the abilities, size and center of gravity of an individual user.

(iii) Delivery Training and Driver Testing

Each user, upon delivery of a custom programmed Interactive Balancing Mobility System, will be required to undergo specialized training at an independent clinic. Both the assessment and the training on the iBOT™ Mobility System will be conducted by individuals who have successfully completed specialized instruction on use, evaluation, customization and training of the iBOT™ Mobility System.

(iv) Distribution of the iBOT™ Mobility System

The iBOT™ Mobility System will only be available from Independence Technology directly through highly trained Product Consultants. Customer service and billing will be managed directly by Independence Technology.[25]

(v) Service and Maintenance: Comprehensive Service and Warranty

Traditional mobility devices have a one-year warranty and DME suppliers average over 17 days to respond to service issues.[26] If users experience a technical problem with the iBOT™ Mobility System, they will call the 24 hour/7 day per week service center for assistance. The device will display a service code and the service center will use the code to determine appropriate resolution. The iBOT™ Mobility System has a two-year warranty on most parts and will include on-site service as a standard component of its service package if the issue cannot be resolved over the phone. The goal of this service model is to have all repairs completed in three (3) business days with minimal disruption to the consumer.

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[25] Independence Technology received its Medicare Supplier number on February 26, 2003.

[26] USA/DIRECT, Inc., September 1996.

G. Estimate of Demand for the iBOT™ Mobility System

Because the iBOT™ Mobility System has no equal in terms of its comprehensive functions and consists of revolutionary technology, a prediction of demand based on sales data is impossible. However, there are several relevant factors that should be considered in estimating potential demand for the product. Only a relatively small subset of wheelchair users could or would benefit substantially from the advanced functionality of the iBOT™ Mobility System. The iBOT™ Mobility System is a complex user-operated device which requires sufficient cognitive and sensory abilities, good abdominal control and balance, and significant coordination. The particular circumstances of each beneficiary's mobility needs and in-home obstacles, as well as their functional aspirations generally, will play a major role in the assessment and prescription process.

Independence Technology's clinical data strongly suggest that at least half the number of wheelchair users have contra-indications preventing them from using the iBOT™ Mobility System. For those without contra-indications, only a small subset may value the additional functions offered by the device enough to prompt a purchasing decision. The financial ability of the beneficiary to afford the cost sharing requirements for purchase of the iBOT™ Mobility System will also be a factor.

(i) Impact of Age on the Demand Estimate

While younger, and more active older, beneficiaries may appreciate the advanced functions of the iBOT™ Mobility System, others—particularly the frail elderly—will find the Stair, 4-Wheel, and Balance modes unnecessary and challenging to operate. Moreover, the Independence Technology business process (See, Section IV, F infra) offers a number of safeguards and clinical evaluations to ensure the beneficiary can safely use the device. As detailed below, this process is more rigorous than that of a Class II mobility device. Due to requirements for safe usage and the contraindications for the iBOT™ Mobility System, the process is more skewed to the younger (e.g., under 65) Medicare beneficiary.

As an initial step, the beneficiary completes the Product Qualification Survey ("PQS"). In addition to identifying contraindications, such as weight and the need for a Tilt and Recline system for activities of daily living or pressure relief, the PQS assesses the need for a Medical Clearance Form from the beneficiary's physician. A copy of the PQS can be found in Appendix D. Initially, some older beneficiaries may have difficulty receiving the medical clearance from their physician to attend the Assessment due to cardiac, pulmonary and fracture risks. The doctor is asked to certify the level of cardiac risk based on the New York Heart Association classification system, the pulmonary risk using the Pulmonary Disability Classification, and the risk of fracture due to severe osteoporosis, recent fracture due to metabolic bone disease or metastatic cancer. See, Appendix E for a copy of the Medical Clearance Form and a description of the various risks contraindicated for the iBOT™ Mobility System.

If the beneficiary is not disqualified due to the PQS and Medical Clearance, they proceed to a free Test Drive of the device. At this point, the beneficiary is calibrated for the device and is able to experience the various functions. This is the stage at which the user tests their comfort

level with the technology and the Balance and Stair Functions. Anecdotally, some older consumers are uncomfortable with the sensation of balancing on two wheels.

After the test drive, the beneficiary undergoes an Assessment where the independent clinician completes the Functional Capacity Evaluation ("FCE") (See, Appendix F.). The FCE tests the ability to maneuver in the device, use the joystick, respond to obstacles, toggle between functions, etc. If after the Assessment the beneficiary is recommended for the device, the device is ordered, manufactured and delivered to the beneficiary's closest iBOT™ Evaluation Center. Upon delivery, a 6-8 hour training session is conducted. At the end of the training, the independent healthcare practitioner administers the Driver's Test which again tests the beneficiary's ability to safely use the device. (See, Appendix G for Driver's Test). The independent clinician must certify that the beneficiary has passed both the FCE and the Driver's Test.

Some older beneficiaries may have difficulty with the cognitive requirements to operate the device safely and effectively, as tested in the FCE and Driver's Test. During the Assessment and the Delivery Training, the independent healthcare practitioner will evaluate the beneficiary's reactions and response time, memory retention of user manual and training content, and the recall and dexterity to sequence among functions. One example includes an evaluation of whether the beneficiary knows when to take their hand off the joystick to avoid obstacles in the various functions of the device (the required stopping distance is longer in Balance Function than it is in Standard Function). Another example is the requirement to remember how to respond to various beeps and warning lights on the device.

Moreover, the beneficiary must demonstrate the visual acuity to see the commands and messages displayed on the User Control Panel. Perception is tested in the beneficiary's capability to gauge step, curb and obstacle heights (e.g., the FDA label indicates the device can climb 5" curbs: the beneficiary needs to assess 5" vs. 6"), to maneuver in tight spaces and awareness of the device and user in the present surroundings. Certain medications might interfere with the beneficiary's ability to demonstrate the capability to use the device safely and effectively by slowing response time. To the extent that older beneficiaries may experience cognitive deterioration, comprehension of the device's capabilities and limitations may be difficult to demonstrate in Assessment and Delivery Training testing.

(ii) "Intent to Purchase" Data

Aside from factors that indicate that the iBOT™ Mobility System will be the most appropriate for a younger demographic, the best indicator of demand derives from Independence Technology's internal market analyses that measured wheelchair users' "intent to purchase" the iBOT™ Mobility System, as well as medical practitioners' willingness to prescribe the device. Two independent research teams projected total iBOT™ Mobility System sales from the survey responses in these studies. Independence Technology then engaged a reputable analyst to examine these studies and forecast demand for purposes of the Medicare program.

After making certain adjustments, the analyst estimated that annual Medicare iBOT™ Mobility System purchases are projected to be in the range of 2,200 to 4,600 units, or about 0.3 to 0.7

percent of annual Medicare wheelchair purchases in the out years. (Because of the time it takes to fully enter the marketplace, Independence Technology anticipates Medicare purchases to be a fraction of this volume estimate in the first three to five years). The percentage is low because about half of existing wheelchair users have contra-indications preventing iBOT™ Mobility System use, and only a small subset of wheelchair users report strong interest in purchasing an iBOT™ Mobility System.[27] The analyst's report is attached as Appendix H.

While these data illuminate the potential demand from Medicare beneficiaries for the iBOT™ Mobility System, Independence Technology recognizes that with Medicare as an entitlement program, the criteria for coverage, as well as the process established for accurate identification and assessment of the most appropriate iBOT™ Mobility System users, are the operative factors in setting demand for this mobility device. Independence Technology is committed to working with CMS to ensure that the iBOT™ Mobility System ultimately reaches those Medicare beneficiaries who can maximize its functions to achieve new levels of health, function and independence, while ensuring that the Medicare program obtains real value for beneficiaries and its investment in this new technology.

H. How Other Payers are Addressing Coverage of the iBOT™ Mobility System

Recognizing the significant benefits that this revolutionary technology offers people with mobility disabilities, other public payers—including several state Medicaid programs and the Veterans Administration—have led the development of alternative coverage criteria specifically designed to be relevant to the iBOT™ Mobility System. One example is New Jersey Medicaid which provides coverage for the iBOT™ Mobility System when beneficiaries are no longer able to use a manual wheelchair, meet product qualifications and who demonstrate a need to climb stairs when performing activities of daily living.[28] New Jersey Medicaid provided its first iBOT™ Mobility System to a New Jersey beneficiary in March 2005. (See, Appendix I.)

Another example of coverage criteria for the iBOT™ Mobility System is the policy published by California's Medicaid program, Medi-Cal, which indicates that the beneficiary must have a medical condition that necessitates the use of a wheelchair and a medical need for "vertical ambulation" within the home.[29] (See, Appendix I.)

In addition, the Veterans Administration ("VA") has purchased eleven (11) iBOT™ Mobility Systems to assess beneficiary reaction. On March 1, 2005, the iBOT™ Mobility System was added to the Federal Supply Schedule. On March 22, 2005 the agency released its Clinical Practice Recommendation for the iBOT™ Mobility System. This document includes the coverage criteria and prescription protocol for the device. Veterans must meet the VA's criteria

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[27] Given that the studies provided in the analyst's report would have difficulty finding reliable data about many of the factors evaluated (e.g., ability to maneuver under a desk or through a doorway, to sequence commands during transitions, reaction time) by the independent healthcare practitioners during the various steps of the Independence Technology business process, it is possible that the percentages will be found to be lower than estimated.

[28] NEW JERSEY DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES, *Medical Necessity Criteria for the iBOT Mobility System* (June 2004).

[29] CALIFORNIA DEPARTMENT OF HEALTH SERVICES, *Durable Medical Equipment Medi-Cal Update* (Dec. 2003).

for a powered wheelchair, have clear functional mobility goals that may be best met by the iBOT™ Mobility System, and meet product qualifications. The full text of these coverage policies has been provided in Appendix J.

V. BENEFIT AND COVERAGE RATIONALE

A. Benefit Category Recommendation

The iBOT™ Mobility System shares a number of function-enabling capabilities with wheelchairs as well as prosthetic devices (e.g., artificial limbs). The following table summarizes these shared characteristics as well as key differences. This comparison illustrates the difficulty of easily categorizing a breakthrough technology, especially one like the iBOT™ Mobility System that offers users a degree of functionality not seen in any other wheeled mobility device.

Function-Enabling Capabilities	Manual Wheelchair	Power Wheelchair	Interactive Balancing Mobility System	Prosthesis (Artificial Limb)
Automatic balancing and dynamic stabilization. Stabilizes the user by instantly and automatically adjusting and balancing itself in response to changes in the individual's center of gravity.			X	
Reach and extension. Allows a user to reach/manipulate objects and move about at a standing-eye level.			X	X
Vertical Ambulation (locomotion in a "standing" eye-level position)			X	X
Climb stairs, curbs and other obstacles.			X	X
Maneuver in confined spaces.	X		X Balance Function	X
Travel across a wide range of variable surfaces including carpet, grass, gravel, mud, sand, snow and steep inclines/declines.	Very Limited	Very Limited	X	X
Mobility on flat, hard surfaces.	X	X	X	X

B. How the iBOT™ Mobility System-IBMS-Meets the 4-Prong Definition of DME

Despite the fact that the iBOT™ Mobility System arguably functions more like a prosthetic device than a power wheelchair, the iBOT™ Mobility System clearly meets the definition of durable medical equipment and CMS should that treat the device along with all of its integrated and interdependent functions as covered DME.

The Medicare statute does not specifically define the term "durable medical equipment" but simply refers to it by example to include "iron lungs, oxygen tents, hospital beds, and

wheelchairs...used in the patient's home...whether furnished on a rental basis or purchased..." 42 U.S.C. Sec. 1395x(n). Regulations interpreting this language were promulgated in 1980, establishing a four prong definition. 42 CFR Sec. 414.202. The regulations state that "durable medical equipment" means equipment, furnished by a supplier or a home health agency that—

1) Can withstand repeated use;
2) Is primarily and customarily used to serve a medical purpose;
3) Generally is not useful to a person in the absence of an illness or injury; and
4) Is appropriate for use in the home.

The following demonstrates how the iBOT™ Mobility System, and all IBMSs, meets the four prong definition of DME and the criteria outlined in §110.1 of the Medicare Benefits Policy Manual ("MBPM"), which elaborates further on the regulatory definition.

(i) Durability

"An item is considered durable if it can withstand repeated use, i.e., the type of item that could normally be rented." MBPM Sec. 110.1.

The iBOT™ Mobility System meets all appropriate ANSI/RESNA and/or ISO standards for mobility devices. It is supported by the results of over 200 individual test cases derived from ISO standards conducted as part of the FDA approval process (See, Appendix K). The iBOT™ Mobility System's principal components are comprised of die-cast aluminum with steel reinforcements and the device is fully intended for and capable of repeated use. The estimated useful life of the iBOT™ Mobility System is similar to the useful life of other mobility devices classified as DME; the typical useful life being five years. In addition, *the iBOT™ Mobility System is available for both rental and purchase.* It is clearly a durable item and precisely meets this prong of the DME definition.

(ii) Medical Equipment

"Medical equipment is equipment primarily and customarily used for medical purposes and is not generally useful in the absence of illness or injury." MBPM Sec. 110.1 This same section of the MBPM considers a "wheelchair" to be equipment that is considered "presumptively medical."

The iBOT™ Mobility System is FDA approved as a Class III medical device and is solely intended for medical use. It cannot be purchased or rented in the absence of an illness or injury which justifies a physician's prescription. Prospective users, whether they seek third party payment or not, must obtain a prescription for the device from a treating physician. This differs from all other wheelchairs and mobility devices that are defined as Class II medical devices, which do not require a physician's prescription to receive such a device. As such, the iBOT™

Mobility System should be considered "presumptively medical" and generally not useful in the absence of an illness or injury, namely, a mobility impairment.

A question has arisen in informal discussions with CMS as to whether certain functions of the iBOT™ Mobility System should be considered "self help" devices or "environmental enhancing mechanisms" and, thereby, not primarily medical in nature. Such functions would include all of the unique aspects of the iBOT™ Mobility System other than standard function; akin to that of a typical power wheelchair.

Section 110.1 of the Medicare Benefits Policy Manual states under a section entitled "Equipment Presumptively Nonmedical" that:

> "other devices and equipment used for environmental control or to enhance the environmental setting in which the beneficiary is placed are not considered DME. These include, for example, room heaters, humidifiers and dehumidifiers, and electric air cleaners. . . .Similarly, . . . self-help devices (such as safety grab bars) . . . are considered nonmedical in nature." MBPM, Section 110.1 [emphasis added].

Splitting the iBOT™ Mobility System into certain functions that are presumptively medical and certain functions that are presumptively nonmedical, even though these functions are interrelated and contained in one, portable device, is an artificial construct that fails to acknowledge the uniqueness of this technology. Climbing stairs and curbs and reaching shelves and cabinets is no more or less an "environmental enhancing" or a "self-help" mechanism than standard power mobility is to achieving simple locomotion. References to "room heaters" and "humidifiers," as well as "safety grab bars," are weak analogies to employ in order to deny coverage of an integrated, multifunctional mobility system. The devices cited by the MBPM are fixtures used to modify the environment of a patient's home in one distinct way (i.e., higher temperature, higher or lower humidity or fixed improvements in safety). In contrast, the iBOT™ Mobility System is an integrated, portable device with multiple functions.

(iii) Appropriate for Use in the Home

While the term "appropriate for use in the home" is not defined in the Medicare statute or regulations, the MBPM states that "a beneficiary's home may be considered his/her dwelling, apartment, a relative's home, a home for the aged or some other type of institution."[30] The iBOT™ Mobility System addresses a comprehensive set of reasonable and necessary medical and functional needs for people who spend their lives using wheeled mobility.

In the home, the iBOT™ Mobility System assists mobility-impaired individuals with simple locomotion on level surfaces, *i.e.,* from point A to point B, as well as a number of important functions not previously available in a single device. It assists the user in traversing soft surfaces such as carpet, variable or rough surfaces, door thresholds, and inclines/declines in and around the home. It also is the first mobility device that allows the user to climb single steps from room

[30] Medicare Benefit Policy Manual (CMS-Pub. 100-02) (hereafter "MBPM"), Ch. 15, § 100.1, *at* http://www.cms.hhs.gov/manuals/102_policy/bp102index.asp.

to room or multiple stairs, enabling access to different levels and different floors within the beneficiary's residence. It balances the user at standing-eye level, assisting with extension of reach to improve the ability to independently perform activities of daily living as well as maneuvering in tight spaces.[31] *CMS' recent adoption of a function-based standard enhances the relevance of the iBOT™ Mobility System's ability to assist individuals in performing MRADLs in home environments where other mobility devices are considered unusable.*

For example, initial users have reported to Independence Technology that they are using the iBOT™ Mobility System to attain access to different floors and sections of their homes in order to perform MRADLs in the home; activities that were simply not possible prior to the ability of their mobility device to climb stairs and single steps. Others have reported that the iBOT™ Mobility System provides secondary access out of the home, i.e., an unramped door, in case of the need for an emergency exit from home due to fire or other reasons. More routine activities that users report being able to perform with the iBOT™ Mobility System include independent meal preparation and access to previously unreachable cabinets, closets, and appliances. While anecdotal in nature, this data is compelling in that it validates the extensive functionality that the iBOT™ Mobility System brings its users in their homes.

Around the home, the iBOT™ Mobility System also assists the user in traversing uneven surfaces such as grass, sand, gravel, and unpaved pathways. The iBOT™ Mobility System enables the user to enter and exit his or her home, access his or her own property, retrieve the mail, and generally perform activities of daily living in the community such as accessing the pharmacy, a physician's office, the grocery store or attending religious services.

The function-enabling capabilities of this mobility system to a select group of Medicare beneficiaries are clear. In addition to the iBOT™ Mobility System's standard function, the stair climbing, step climbing, and "standing" functions are of major benefit to beneficiaries "in the home" for the purpose of performing MRADLs. For those who have additional mobility needs, the added value of the device to operate in 4-Wheel function, climb curbs, traverse rough surfaces, and raise the seated user to eye level while both stationary and during locomotion is useful in, but extends beyond, the four walls of the beneficiary's residence.[32]

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[31] To quote from the NCD for MAE, "individuals who used wheelchairs have lower MRADL function without the wheelchairs than individuals using other mobility aids and wheelchair users required more personal assistance than did users of other mobility aids." The same study found that canes and crutches reduce hours of personal care while wheelchairs and walkers increase hours of personal care but that wheelchair and walker users had more limitations in daily living tasks. However, the study went on to say, it is hard to imagine that a cane or crutch could be sufficient intervention to reduce environmental demand to the point of performance of more complex activities such as housework and cooking, without human help or substantial modification to the home environment. Clearly, the iBOT™ Mobility System, with the ability to elevate above a standard stovetop and countertop as well as reach high shelves, allows the user in many situations to cook and do housework independently without substantial modification to the home environment.

[32] Stuifbergen, et al. found that interventions to enhance social support, decrease barriers, and increase specific self-efficacy increase health-promoting behaviors and quality of life. The iBOT™ Mobility System offers the ability to enhance social interaction and decrease barriers through the 4-Wheel and Balance Functions.

C. The iBOT™ Mobility System's Unique Functions are Covered DME Benefits

Based on the foregoing analysis, the iBOT™ Mobility System meets the four-prong definition of durable medical equipment and, thus, should be a covered DME benefit under the Medicare program. CMS essentially confirmed this view with its issuance of Transmittal 35 in December 2003,[33] which was apparently prompted by FDA approval of the iBOT™ Mobility System several months earlier and the question as to how the device should be coded for claims' submission purposes. However, in the absence of a National Coverage Determination on the iBOT™ Mobility System, Transmittal 35 reflected the fact that the agency did not adequately consider or address the extensive functionality that the device brings to beneficiaries.

Without a National Coverage Determination to guide CMS, and considering the innovative nature of the device, Transmittal 35 addressed the iBOT™ Mobility System by essentially "crosswalking" a number of the unique functions of the iBOT™ Mobility System to other, unrelated devices that shared one or more characteristics with the device. Transmittal 35 also failed to recognize some of the key functions of the iBOT™ Mobility System entirely, such as its 4-Wheel function. This approach resulted in CMS treating the iBOT™ Mobility System as a power wheelchair base with added functions that were considered, for the most part, non-covered benefits.

Separating the integrated functions of the iBOT™ Mobility System into discrete "add-on" features is contrary to the design of the device and fails to adequately recognize the potential of this device to help achieve MRADLs. *Independence Technology strongly disagrees with this approach and, through this NCD request, urges CMS to take a fresh look at its coverage analysis of this innovative technology.*

As already stated, the unique functions of the iBOT™ Mobility System —stair and curb climbing, 4-Wheel function, and seat elevation (or "balance" function)—are all reliant upon the iBOT™ Mobility System's iBALANCE™ Technology. The iBALANCE™ Technology permits these functions to work interdependently with the "hardware" and battery that powers the standard function of the device. In other words, the iBALANCE™ functions of the device are inherent in the overall system. As such, it is inappropriate to treat these functions for coverage and payment purposes as "add-on" features to a traditional power wheelchair base. These functions are fully integrated into the device and, taken together, form the very nature of the iBOT™ Mobility System.

If the iBOT™ Mobility System is determined by CMS to be "primarily medical in nature" while operating in standard function, then assuming that the other three prongs of the DME definition are satisfied, the device itself must be considered covered DME. Whether additional functions of the device are considered *reasonable and necessary* for purposes of coverage of specific beneficiaries is another inquiry, but the device itself is no different when in standard function versus other functions. ***The threshold determination that the device meets the four-prong definition of DME should not turn on which one of the many functions of the device is***

[33] One-Time Notification (CMS-Pub. 100-20), Trans. No. 35, Change Request No. 3020 (Dec. 24, 2003), *at* http://www.cms.hhs.gov/manuals/120_OTN/default.asp.

engaged at any given moment. The question is whether the device, as a whole, meets the four-prong definition of DME, including that the device is primarily medical in nature. CMS has essentially acknowledged this through its issuance of Transmittal 35.

The iBOT™ Mobility System's features, whether taken separately or taken as an integrated set of functions, should be considered both covered benefits and reasonable and necessary for specific beneficiaries. With respect to whether each of the principal functions of the iBOT™ Mobility System are covered DME benefits, we offer the following analysis:

(i) Standard Function

In standard function, the iBOT™ Mobility System operates similar to a traditional power wheelchair and, thus, this function of the device is covered under the DME benefit as CMS has previously acknowledged. In this function, the battery power is activated, but the iBALANCE™ Technology is not active. In addition to being durable, the device should be considered "presumptively medical," similar to traditional power wheelchairs. Because power wheelchairs are routinely considered to meet the requirement that they are "primarily medical in nature," the iBOT™ Mobility System while operating in standard function should also satisfy this aspect of the DME definition.

(ii) Stair Climbing

Until recently, Medicare program guidance did not explicitly state whether the program covers "stair climbing" under the durable medical equipment benefit. Despite the lack of direction from the statute, regulations, or program manuals, Transmittal 35 states that, with respect to the iBOT™ Mobility System, the "stair climbing feature for this device should be billed using HCPCS A9270 ("Non-covered item or service")."[34] Transmittal 35 offered no authority or analysis to support this preliminary conclusion.

It is clear that the Medicare program does not consider "stairway elevators" to meet the definition of DME, deeming such items to be primarily for patient convenience and not sufficiently medical in nature. According to Medicare program guidance, claims for stairway elevators and similar devices must be denied because of the statutory definition of durable medical equipment.[35] The guidance specifically states that "[e]quipment which basically serves comfort or convenience functions or is primarily for the convenience of a person caring for the patient, such as elevators, stairway elevators, posture chairs, and cushion lift chairs do not constitute medical equipment."[36]

Independence Technology believes it is inappropriate to rely on this guidance as support for a determination that the stair climbing function of the iBOT™ Mobility System is a non-covered benefit. The iBOT™ Mobility System is not a "stairway elevator." A "stairway elevator" is essentially a home modification that is stationary and affixed to one stairway in a home or

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[34] *Id.*

[35] Medicare Coverage Issues Manual (CMS-Pub. 6) § 60-9.

[36] MBPM, Ch. 15, § 110.1.B.2.

building. This is inherently different from the iBOT™ Mobility System's capabilities, which enable the user (solo or with assistance) to ascend and descend many different types of standard stairways while remaining in the same mobility device that operates in standard function. The integration of the stair climbing function into the device renders the analogy to any of the items listed in the existing guidance, e.g., stairway elevators, irrelevant to this NCD on the iBOT™ Mobility System.

The fact that the iBOT™ Mobility System allows the rider to remain seated in the same device during stairclimbing and other functions is a major safety issue. Fewer transfers from one device to another means fewer falls and associated injury/treatment. Coupled with the iBALANCE™ technology's ability to dynamically adjust the seating position of the user regardless of the function being performed or terrain being traversed, the iBOT™ Mobility System is a highly stable and safe device.

During the public hearing on Independence Technology's HCPCS application for the iBOT™ Mobility System held on June 23, 2005, CMS representatives raised an issue that the iBOT™ Mobility System is not the only way that beneficiaries can climb stairs. The CMS representative stated that out of necessity, wheelchair users have found alternative methods for ascending and descending stairs such as reliance on a caregiver or passerby carrying the person up or down the stairs, "bumping" up and down the steps on the person's buttocks without the wheelchair, sliding down on handrails or the use of other stair-dedicated equipment (e.g., stairglide).

Independence Technology believes that each of these techniques presents significant risks to patients and/or is often impractical. Most power wheelchairs can safely carry a user up to at least 250 pounds. It is hard to imagine that there are many caregivers who can safely carry even 150 pounds up and down a flight of stairs. "Bumping" is limited to those beneficiaries who possess the physical functionality (e.g., upper body strength) and medical condition (e.g., skin integrity) to perform this stair climbing maneuver. There is a clear safety issue with any beneficiary who is expected to slide down handrails on one's hands in order to gain access to another level of the home. Other equipment on the market addresses stair climbing only and requires multiple transfers as well as multiple mobility devices for the top and bottom of the stairs. The iBOT™ Mobility System permits a seamless transition for the beneficiary from standard function to stair climbing and back to standard function, all the while comfortably and safely seated in the device itself.

(a) *The iBOT™ Mobility System is Sufficiently Medical:* As a Class III medical device, the iBOT™ Mobility System, with its stair climbing capability, is primarily and customarily used for medical purposes and is not generally useful in the absence of illness or injury. Moreover, as a Class III medical device, it is not available to anyone without a physician's prescription (regardless of insurance requirements). This demonstrates how inappropriate it is to determine the coverage status of the iBOT™ Mobility System's stair climbing function based on previous determinations of non-coverage for non-medical, free-standing items, such as stairway elevators. The ability of a beneficiary to negotiate a flight of stairs in their home in order to perform or increase participation in MRADLs is no less "medical in nature" than using the iBOT™ Mobility System's standard function to

accomplish other MRADLs, particularly when both functions are integrated into the same device.[37]

(b) *The iBOT™ Mobility System is Not a Comfort, Convenience, or Luxury Item:* In addition to the inability to walk upright on one's lower limbs, the inability to ascend and descend stairs is perhaps the single most defining characteristic of what it means to have a physically disabling mobility impairment. Without this ability, a non-ambulatory person is either reliant on accessible features built into the environment or must be resigned to living life on one dimension; the ground level. Achieving access to different floors and levels within one's home or other buildings is no more of a convenience or luxury for a person with a mobility impairment than walking itself, and Medicare clearly covers devices that assist and/or substitute for walking.

Given CMS' shift from the "bed or chair confined" standard to functional need and consideration of the beneficiary's home environment in the NCD for MAE, we believe that Medicare's current MAE coverage policy is very consistent with the extension of coverage to the iBOT™ Mobility System in order to meet the need for stair climbing, and greater access in the home generally. If stair climbing is required in one's home in order to perform or more fully participate in MRADLs, then assuming other aspects of the coverage policy are met, CMS should cover this function of the device in certain circumstances. In fact, number of studies cited in the NCD for MAE were supportive of coverage of the kind of functionality offered by the iBOT™ Mobility System.

> One study documented selected consequences of unmet need. Falling because of lack of assistance in the home, inability to maintain special diets, and inability to eat or drink when hungry or thirsty may force a transition from community to institutional living. Missing medical appointments and inability to fill prescriptions or to obtain medical supplies may disrupt compliance with medical regimens and compromise medical management of chronic health conditions.[38] The increased functionality and independence provided by the iBOT™ Mobility System has significant potential to reduce unmet need and thereby have a positive net health outcome on the beneficiary. First, it may allow for safer access to other parts of the home with the potential to reduce falls. Second, the ability to reach items in the refrigerator, freezer and on the stovetop allows for continuous, easier and potentially safer access to the beneficiary's food. Third, the ability to reach the doctor or pharmacy, even if there are not curb cuts in the sidewalk or if there is a step into the office, improves access to timely medical care. A number of current iBOT™

[37] As noted previously, to the extent the Stair Function can be used to provide access to a diversity of healthcare facilities – access that might otherwise require assistance of a care-giver or result in delay or neglect of necessary healthcare – there are medical benefits to reducing environmental barriers to care.

[38] Allen SM, Mor V. The prevalence and consequences of unmet need; contrasts between older and younger adults with disability. Medical Care 1997;35(11):1132-48.

Mobility System consumers have used the device to reach parts of their home they have not seen since their accidents or onset of their disability. In some cases this allowed access to their children's bedrooms, enhancing family care.

There is simply no clinical basis to deny people with disabilities access to a presumptively medical device that not only permits simple battery-powered locomotion but also allows the person to ascend and descend stairs. This is particularly true when one considers that the Medicare program routinely covers other items and services that enable stair climbing for beneficiaries who, with that item or service, can become ambulatory stair climbers. (See, Section V, D, *infra*, discussing the reasonable and necessary standard.)

For the foregoing reasons, the stair climbing function of the iBOT™ Mobility System, a function that is fully integrated into a presumptively medical device and improves net health outcomes in the beneficiary's home, should be considered a covered DME benefit. To protect the Medicare program and ensure the beneficiary receives the least technology to meet the patient's needs, Medicare could adopt the VA coverage policy which requires a demonstrated need for stair climbing.[39]

(iii) Traversing Variable Surfaces

The Medicare statute, regulations, and program guidance do not explicitly state whether the program covers mobility devices that are designed to traverse variable surfaces, *e.g.,* 4-Wheel function, whether inside or outside of the home. As already stated, this feature of the iBOT™ Mobility System was not addressed in Transmittal 35 which, understandably, was issued by CMS with limited information about the device.

4-Wheel function permits the iBOT™ Mobility System to traverse variable surfaces and is fully integrated into the iBALANCE™ Technology. As an integrated feature of the device, 4-Wheel function is not severable from the remaining functions of the iBOT™ Mobility System. This function permits the user to negotiate single stairs or curbs, door thresholds, thick carpet and variable surfaces in and around the home. It also permits extensive maneuverability in both the natural and man-made environments outside of the home.

There are many examples of how the ability to traverse a variety of surfaces, as provided by the iBOT™ Mobility System, could improve net health outcomes by removing barriers to healthcare and health-enhancing activities. Individuals who experience a physical disability are faced with many obstacles that may limit their ability to engage in physical activity and/or exercise. Some of these obstacles originate from the very nature of their physical limitation (i.e., their functional abilities). Other limitations result from the environment itself, such as lack of access to adequate transportation and/or exercise facilities. Together these obstacles promote a high incidence of sedentary lifestyles among adults with physical disabilities.[40, 41, 42] Furthermore, the physical and

[39] See, Appendix H for VA coverage criteria.

[40] Dearwater SP, LaPorte RE, Cauley JA, Brenes G. Assessment of physical activity in inactive populations. Med Sci Sports Exerc 1985;17:651-55.

environmental limitations that exist for these individuals can lead to a downward spiral in terms of both their health and well being.[43, 44, 45, 46]

Like stair climbing and standard function, the 4-Wheel function may provide a select set of Medicare beneficiaries with the ability to perform or meaningfully increase their participation in MRADLs. A fundamental feature of what is otherwise a presumptively medical device, the 4-Wheel function of the iBOT™ Mobility System is of selective use in the home (as well as outside the home) for a subset of Medicare beneficiaries whose home environment renders traditional mobility devices unusable. The Balance Feature of the iBOT™ Mobility System, therefore, should be a covered DME benefit.

(iv) Seat Elevation

According to Transmittal 35, seat elevation is properly billed using HCPCS E2300 ("Power wheelchair accessory, power seat elevation system). This HCPCS code was established in fiscal year 2004, and coverage is currently left to carrier discretion. Of the four DMERC regions, all four have promulgated local medical review policies ("LMRPs") governing coverage of seat elevation systems. According to these coverage decisions, "[a] power seat elevation feature (E2300), power standing feature (E2301), and power wheelchair attendant control (E2331) are non-covered because they are not primarily medical in nature."[47]

Seat elevation for people who are long term wheelchair users can significantly improve net health outcomes in at least two ways. First, it provides the wheelchair user with improved access by expanding the user's reach primarily inside the home but also outside of the home in certain circumstances. The ability to reach is critical to the performance of a number of MRADLs. In-home access—to mirrors and medicine cabinets for grooming, to closet shelves and washing machines for dressing, to kitchen cabinets, refrigerators, freezers and stovetops for eating/preparing meals—is severely limited without the ability to adequately reach. One iBOT™ Mobility System consumer with a spinal cord injury, a New Jersey Medicaid beneficiary,

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[41] Graitcer PL, Maynard FM. First colloquium on preventing secondary disabilities among people with spinal cord injuries. Atlanta, GA: US Department of Health and Human Services, 1990.

[42] Hjetnes H, Vocak Z. Circulatory strain in everyday life of paraplegics. Scand J Rehab Med 1979;11:67-73.

[43] In a study of persons with orthopedic impairments, Nosek found the level of independence to be related to health status, defined both in terms of use of medical services and health-promoting practices. Those individuals with high levels of social independence reported using emergency medical care less frequently, spent fewer days in the hospital, tended not to smoke, and spent 2-5 hours per week in planned physical activity.

[44] Hoffman MD. Cardiorespiratory fitness and training in quadriplegic and paraplegics. Sports Med 1986;3:312-30.

[45] Nosek, M. Relationships among measures of social independence, psychological independence, and functional abilities in adults with severe orthopedic impairments. Unpublished doctoral dissertation, The University of Texas at Austin, 1984.

[46] Becker HA, Stuifbergen AK, Ingalsbe K, Sands D. Health promoting attitudes and behaviors among persons with disabilities. Int J Rehab Research 1989;12(3):235-50.

[47] *Wheelchair Options/Accessories*, Region A DMERC, LMRP No. L11473; *Wheelchair Options/Accessories*, Region B DMERC, LMRP No. 4987; *Wheelchair Options/Accessories Policy Article*, Region C DMERC, Article A20284; *Wheelchair Options/Accessories*, Region D DMERC, LMRP No. L11462.

indicated he would no longer need his personal assistant for meal preparation due to his improved ability to reach. Second, seat elevation offers important psychosocial benefits to the wheelchair user by allowing interaction with family members, friends, colleagues and other individuals at a more appropriate level (e.g., at standing-eye level). A number of iBOT™ Mobility System users have testified that this aspect of the iBOT™ Mobility System, primarily through the standing feature, has helped restore their "dignity."

The iBOT™ Mobility System permits two types of seat elevation. When the device is in 4-Wheel function, the seat can be raised up to ten inches (10")—28" from the floor—or in "balance" function, the seat can be raised up to fourteen inches (16")—34" from the floor—activated through the control pad. The device itself may also be raised into "standing" or "balance" function, where the device balances on two wheels through the use of gyroscopes and redundant computer systems and the seated user is raised to standing-eye level. The iBOT™ Mobility System is fully operational while the device is in the balance function, permitting safe and stable mobility, movement in confined spaces, extension of reach for the user, and standing-eye level interaction with others.

It is not clearly understood—nor is it supported by any clinical or other data—why the Medicare program has apparently determined that extending the reach and achieving standing eye-level height for a person who spends his or her life in a seated position is not covered. These functions can be just as important to the mobility-impaired beneficiary as the ability to move from point A to point B. CMS' policy on seat elevation seems to make little sense in light of Medicare's NCD for MAE and CMS should take this opportunity to revisit its position on this issue. The current NCD for MAE assesses the need for wheeled mobility based on the ability to perform or increase participation in in-home MRADLs, many of which would be significantly impacted by the ability to improve extension and the ability to reach. In fact, there are examples in other areas of Medicare's existing benefit that contradict its current policy on seat elevation.

Medicare currently provides coverage for rehabilitation services, i.e., therapies that aim to improve a beneficiary's "range of motion."[48] Range of motion is an important factor in a beneficiary's ability to maximize the ability to reach. In addition, recently, CMS approved a National Coverage Determination covering functional neural electrical stimulation in beneficiaries with spinal cord injuries to enhance the potential for standing and, ultimately, walking.[49] These analogies provide a basis on which Medicare should rely to extend coverage to rehabilitation technologies that can achieve the same outcome for non-ambulatory beneficiaries.

Although the four DMERCs have weighed-in with their view of coverage for seat elevation or a "standing" feature, CMS central has not publicly focused its attention on this coverage issue to date and has recently issued the NCD for MAE which seems to heighten the importance on the ability to extend one's reach. Of the five MRADLs cited in the NCD (toileting, feeding, dressing, grooming and bathing), virtually all of them could be materially advanced through an

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[48] See, *e.g.*, 42 C.F.R. § 483.25(e) (requiring, as a condition of participation, that a skilled nursing facility provide treatment to improve range of motion in residents where range of motion is limited).

[49] Medicare National Coverage Determinations Manual (CMS Pub. 100-03) § 160.12, *at* http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp.

improvement in the ability of a seated person to extend one's reach. Therefore, we request that CMS make a comprehensive assessment of the importance of recognizing seat elevation under the DME benefit for the long term mobility device user, particularly when the seat elevation mechanism is integral to the full functioning of the mobility device, such as the iBOT™ Mobility System.

Many people with mobility disabilities report that one of the most degrading and frustrating aspects of long term wheelchair use is the inability to achieve a standing height to perform manual tasks or extend one's reach to accomplish activities of daily living that are taken for granted by others. Comparable to the value of the stair climbing feature for beneficiaries with disabilities, seat elevation and/or the "standing" feature of the iBOT™ Mobility System are no less "medical" than simple locomotion. Coupled with the improved functionality that seat elevation can bring to beneficiaries in the home, as described above, the seat elevation function of the iBOT™ Mobility System should be a covered DME benefit.

D. Establishing that the iBOT™ Mobility System is Reasonable and Necessary

The Medicare program covers items and services when they are determined to be "reasonable and necessary." 42 U.S.C. Sec. 1395y(a)(1). Current coverage policies that have been developed for other mobility devices (*i.e.,* wheelchairs and POVs) are not sufficient to define reasonable and necessary coverage criteria for the unique functions of Interactive Balancing Mobility Systems, represented by the iBOT™ Mobility System.

Recently, CMS has used the concept of "net health outcomes" to assess the medical necessity of new technologies. According to recent CMS decision memoranda (which state CMS's intention to issue an NCD), CMS attempts to assess whether an intervention or technology's benefits to Medicare beneficiaries outweigh its harms. Important in this calculation is whether the benefits are clinically significant and longstanding, rather than marginal or short-lived. Independence Technology believes this standard is clearly met by the iBOT™ Mobility System and that the device does indeed, improve net health outcomes for beneficiaries with mobility disabilities. The remainder of this NCD request seeks to demonstrate why we believe the reasonable and necessary standard has been met in this case.

The terms "reasonable" and "necessary" have been specifically interpreted in Medicare guidance. Failure to meet these standards will:

> "bar payment for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case or will permit only partial therapeutic function in an individual case or will permit only partial payment when the type of equipment furnished substantially exceeds that required for the treatment of the illness or injury involved." [50]

[50] MBPM, Ch. 15, § 110.1.

Medicare guidance specifically defines medical *necessity* as follows:

> "Equipment is necessary when it can be expected to make a meaningful contribution to the treatment of the patient's illness or injury or to the improvement of his malformed body member." [51]

With respect to the requirement that the item or service be *reasonable*, Medicare guidance states that the following questions should be considered:

- Would the expense of the item to the program be clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment?
- Is the item substantially more costly than a medically appropriate and realistically feasible alternative pattern of care?
- Does the item serve essentially the same purpose as equipment already available to the beneficiary? [52]

(i) The iBOT™ Mobility System Meets the Standard of Medical Necessity

The iBOT™ Mobility System is equipment that meets the test for medical necessity because it clearly provides a "meaningful contribution to the treatment of a beneficiary's illness or injury," *i.e.,* a mobility impairment.[53] The iBOT™ Mobility System breaks new ground in terms of increased function for beneficiaries with mobility impairments in a way that has the real potential to improve people's lives in a significant way. Previously, Medicare beneficiaries have been limited in the level of functional restoration achievable by traditional DME mobility systems—manual wheelchairs, power wheelchairs and POVs. No other single wheelchair or POV restores the full complement of basic physical functions like Interactive Balancing Mobility Systems such as the iBOT™ Mobility System.

For instance, it bears repeating that the iBOT™ Mobility System enables the user to independently ascend and descend stairs, steps and curbs, balance at standing-eye level while in a fixed position or in motion, cross variable surfaces both inside and outside of the home, and, of course, perform simple power locomotion as well. The device permits better performance of activities of daily living, both "horizontal" ambulation as well as "vertical" ambulation, and other activities that involve balance, mobility, extension and reach including MRADLs such as

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[51] *Id.*

[52] *Id.*

[53] *Id.*

eating, grooming and dressing. These capabilities constitute a series of functions that are clearly tied to one's ability to remain healthy, functional, and independent.[54, 55]

The iBOT™ Mobility System introduces functions to Medicare beneficiaries with mobility impairments that have never before been possible, particularly in a single device. It is critical that CMS give sufficient weight to these improvements in function during its consideration of whether the device offers beneficiaries a meaningful contribution to the treatment of their mobility impairment.

The iBOT™ Mobility System has real potential to address many of the unmet needs in performing mobility related activities of daily living. As stated in the final NCD for MAE, a beneficiary's home environment may dictate which device is required to meet basic needs in the home. While a manual wheelchair, POV or power chair may meet some MRADL needs of a beneficiary, such devices will seldom help the individual who needs access to another level or floor of their house to perform these activities.

Moreover, to the extent that the algorithm in the final NCD for MAE considers the safety of a prescribed device, CMS needs to consider how the beneficiary would otherwise reach a stovetop, exit the home, reach a high shelf or maneuver up steps and stairs. Is the alternative as safe as an integrated device such as the iBOT™ Mobility System that has been thoroughly tested against RESNA and ISO standards in order to gain FDA approval? Or is the alternative a set of homemade adjustments made to existing fixtures? Or is there no alternative that allows safe access around and in and out of the home?[56]

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[54] Hoenig, et al. 2003, referenced in the final NCD for MAE, found that there was also a strong and consistent relationship between the use of MAE, including wheelchairs, and requiring fewer hours of personal assistance to perform MRADLs. People who do not use equipment report about 4 more hours of help per week compared with those who do not use equipment. Both Agree and Verbrugge showed that persons relying on technological assistance reported less residual disability than did those relying on personal assistance, particularly those with arthritis or with mild or moderate physical impairment or dependencies in lower-extremity function. The beneficial effects of technological assistance on ADL performance in turn would be expected to reduce the level of personal assistance needed to cope with ADL deficits. The iBOT™ Mobility System, with its functional capabilities, has the potential to further reduce the need for personal assistance by increasing a user's independence more than a standard power chair.

[55] Hoenig H, Taylor DH Jr, Sloan FA. Does assistive technology substitute for personal assistance among the disabled elderly. Am J Public Health 2003 Feb;93(2):330-7.

[56] Historically, Medicare has recognized ambulation or locomotion from point A to B as a medical need—largely because technology available at the time was limited to such movement. The new functional standard for mobility assistive equipment allows CMS to consider the varied living situations of its beneficiaries. As stated in CMS' MAE final determination, the beneficiary's environment is relevant to the determination of the appropriate form of mobility assistance that should be employed. This is because the new coverage policy is geared toward the ability of a MAE to improve participation in MRADLs in the home. Conventional thinking would lead one to compare the iBOT™ Mobility System to a power mobility device and restrict evaluation of the reasonable and necessity standard to this single category of devices. Because of the breakthrough capabilities of the iBOT™ Mobility System, however, the true measure of the terms "reasonable and necessary" in the IBMS context is no longer limited to horizontal ambulation or locomotion (i.e., going from point A to point B). The new measure should be the ability of the iBOT™ to improve participation in and performance of MRADLs through the unique features of the device.

It is not sufficient for the Medicare program to simply state that functions such as stair climbing, 4-Wheel function, and seat elevation or the "standing" function are not medically necessary when, prior to the introduction of Interactive Balancing Mobility Systems such as the iBOT™ Mobility System, these functions were not even achievable, let alone available in one multi-functional mobility device. Particularly in light of Medicare's recent NCD for MAE, CMS should revisit its previous coverage decisions in this area and bring them into compliance with the intent of the NCD for MAE; to cover mobility devices based on their ability to improve performance and/or participation in MRADLs in order to improve "health, well-being, and quality of life." See, Appendix L; NCD for MAE, page 2 of 18. The iBOT™ Mobility System meets this standard and should, therefore, be covered by Medicare for a select group of beneficiaries.

(ii) Assessing the Reasonableness of the iBOT™ Mobility System: Is the Benefit Worth the Expense?

The reasonableness prong of the "reasonable and necessary" standard is met in this case, in part, by determining whether the expense of the iBOT™ Mobility System is "clearly disproportionate to the therapeutic benefits which could ordinarily be derived from use of the equipment."[57] This is a determination that seems to be subject to the perspective of the decision maker. For instance, to the mobility-impaired beneficiary who has spent ten years on one floor of his or her house, unable to reach the kitchen cabinets and virtually "shut in" to the four walls of the home, the therapeutic benefit of climbing stairs, extending reach, traversing variable surfaces and meaningfully participating in MRADLs as well as other activities is of great value.

In contrast, in the absence of a National Coverage Determination, Medicare issued a preliminary determination in Transmittal 35 that the stair climbing function, 4-Wheel function, and seat elevation or "standing" function of the iBOT™ Mobility System should be coded in such a way as to essentially deny coverage of these functions. This position exposes the different treatment that non-ambulatory Medicare beneficiaries seem to receive to in contrast to ambulatory beneficiaries.

(a) *The Cost/Benefit of Stair Climbing:* The Medicare program covers items and services related to stair climbing for ambulatory beneficiaries. With respect to the home health benefit, for instance, Medicare program guidance states that covered skilled therapy services include "gait training."[58] The Medicare Benefit Policy Manual provides the following example of covered "gait training:"

> "A patient who has had a total hip replacement is ambulatory but demonstrates weakness and is unable to climb stairs safely. Physical therapy would be reasonable and necessary to teach the patient to climb and descend stairs safely."[59]

[57] MBPM, Ch. 15, § 110.1.

[58] MBPM, Ch. 15, § 40.2.2.C.

[59] *Id.*

Thus, although the focus of the covered therapy is to teach the patient how to climb stairs safely, presumably to prevent falls in the future, the Medicare program recognizes that stair climbing is an integral function that is routinely required in a patient's home and provides coverage for services related to restoration of that function.

The same inequitable treatment that can be seen as it relates to therapy services that assist beneficiaries with climbing stairs can also be seen in Medicare's coverage policies for devices as well. Though Transmittal 35 states that it will not cover technology that allows wheelchair users to ascend and descend stairways, the program does cover technology for purposes of allowing ambulatory beneficiaries to achieve this same goal.

For example, Medicare currently covers a microprocessor-controlled prosthetic knee, commonly known as the "C-Leg." The C-Leg uses sensors and a microprocessor to improve the performance of the prosthesis, particularly on barriers such as stairs. In 2002, Medicare received 595 claims for C-Leg components, only rejecting 74 of these claims (12.44 percent). The fee schedule amounts for the C-Leg component range from $11,160.13 to $14,880.17—not including the remainder of the prosthesis which typically brings the total cost of the finished prosthetic limb to $30,000 or more.

The C-Leg is potentially analogous to the iBOT™ Mobility System because: (1) it provides the beneficiary with significantly improved performance over variable surfaces, including stair climbing; and (2) it is significantly more expensive than less functional prosthetic technology.

Thus, the Medicare program does not currently permit coverage of stair climbing technology for non-ambulatory patients but does cover both rehabilitation services and devices for patients who are ambulatory or potentially ambulatory. This different treatment appears to discriminate between groups of beneficiaries in a manner that has no clinical or legal basis. As such, we urge CMS to consider this factor as it analyzes potential coverage of the stair climbing function when that function is integrated into a mobility device, such as the iBOT™ Mobility System, which is otherwise considered covered DME.

(b) *The Cost/Benefit of 4-Wheel Function:* Reliable and safe access across steps, curbs and variable surfaces has tremendous potential to improve functional independence in and around the home. The safety of wheelchair use in the home is enhanced with, for example, the ability to access two exits out of the house (where today only one may have a ramp) and the ability to elevate the seat of a mobility device to safely pull items from the stove. While Transmittal 35 and the Medicare program guidance does not specifically address coverage of the "4-Wheel" function of the iBOT™ Mobility System, the program guidance does address an analogous situation, again, in the area of lower limb prosthetics. The Medicare program provides coverage for prosthetic

components that permit beneficiaries to traverse variable surfaces. For certain prosthetic components, the Medicare program will only deem the prosthetic component to be medically necessary if the beneficiary is assigned to a certain "functional level" by his or her physician. There are five functional levels and they appear in the Medicare guidance as follows:

> Level 0: Does not have the ability or potential to ambulate or transfer safely with or without assistance and a prosthesis does not enhance their quality of life or mobility.
>
> Level 1: Has the ability or potential to use a prosthesis for transfers or ambulation on level surfaces at fixed cadence. Typical of the limited and unlimited household ambulator.
>
> Level 2: Has the ability or potential for ambulation with the ability to traverse low level environmental barriers such as curbs, stairs or uneven surfaces. Typical of the limited community ambulator.
>
> Level 3: Has the ability or potential for ambulation with variable cadence. Typical of the community ambulator who has the ability to traverse most environmental barriers and may have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
>
> Level 4: Has the ability or potential for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels. Typical of the prosthetic demands of the child, active adult, or athlete.[60]

Medicare will cover more advanced (and more expensive) prosthetic components for beneficiaries who are assigned to higher functional levels. For example, for an individual who is categorized as functional level 1, Medicare only covers a basic prosthetic foot (*e.g.,* SACH foot, reimbursement for which is generally between $162.88 and $217.17). In contrast, for an individual who is categorized as functional level 3 or higher, Medicare will cover a more technologically advanced prosthetic foot that may be significantly more expensive (*e.g.,* Flex Foot system, reimbursement for which is generally between $2,973.47 and $3,964.62). Similar price differences are found in other prosthetic components.

Once the components are assembled into a complete artificial limb, the result is that Medicare will pay in excess of $30,000 to provide an amputee with a highly advanced prosthesis so that the amputee can cross variable surfaces and otherwise ambulate in the home and community. Understanding that the "in the home" requirement applies to DME but not prosthetics, there is nonetheless a clear inconsistency in what Medicare covers for ambulatory verses non-ambulatory beneficiaries. Much like the functional levels that Medicare developed to accurately link advanced prosthetic

[60] Lower Limb Prostheses, DMERC Regions A, B, C, & D LMRPs (emphasis added).

technology with those beneficiaries who could benefit the most, CMS should seriously consider applying similar logic to the IBMS (represented by the iBOT™ Mobility System) for those beneficiaries who have the greatest potential functional improvement with the device. Since the device is a fully integrated mobility system that includes 4-Wheel functionality in the overall operating system, CMS should recognize coverage of the 4-Wheel function under the DME benefit and reimburse the device accordingly.

(c) *The Expense of the iBOT™ Mobility System is Reasonable*: In the case of both stair climbing and 4-Wheel functionality, and to a lesser extent the seat elevation or "standing" function, the question of whether the therapeutic benefit of the iBOT™ Mobility System is clearly disproportionate to the expense for the device appears to be dependent upon the individual circumstances and medical/functional needs of the beneficiary. Now that a device exists that incorporates all of these functions into its overall design, functions such as climbing stairs in one's home and extending one's reach become functions that are far more relevant and worthy of therapeutic intervention than they were when no device existed that could enable such greater participation in all types of activities of daily living, including the five examples listed in the NCD for MAE. As a frame of reference, the cost of the iBOT™ Mobility System is currently $26,100. It is our strongly held view that the expense of the iBOT™ Mobility System is reasonable when balanced against the comprehensive set of functions that the device provides to mobility-impaired beneficiaries, especially when compared to other areas of the Medicare benefit that serve ambulatory patients.

(d) *Less Costly, Alternative Patterns of Care:* As part of the cost/benefit equation, Medicare will also examine whether the iBOT™ Mobility System is "substantially more costly than a medically appropriate and realistically feasible alternative pattern of care."[61] This standard will clearly not be met by a subset of Medicare beneficiaries whose in-home environment is such that without an iBOT™ Mobility System, the beneficiary simply will not be able to perform or participate in MRADLs. For this segment of the Medicare population, there will be no less costly alternative pattern of care. For the beneficiary who can take maximum advantage of the iBOT™ Mobility System's functions, there is simply no other single mobility device on the market today, or alternative set of medical interventions, that would be a realistically feasible alternative.

Similarly, the third prong to the reasonableness inquiry focuses on whether there are other devices that "serve essentially the same purpose as the equipment already available to the beneficiary."[62] Again, because of the breakthrough nature of this new technology and the extensive combination of functions it provides in one, integrated device, there is no other device that serves essentially the same purpose as the iBOT™ Mobility System. If the iBOT™ Mobility System would serve essentially the same purpose as a power wheelchair for a particular beneficiary, then it would not

[61] MBPM, Ch. 15, § 110.1.

[62] *Id.*

be considered reasonable and necessary. But for those beneficiaries who will be able to use the iBOT™ Mobility System to meaningfully increase their participation in and performance of MRADLs, particularly because their in-home environment does not accommodate traditional mobility devices, then this standard will be met. As such, for a select group of Medicare beneficiaries, the iBOT™ Mobility System meets the "reasonable and necessary" requirement of the Medicare program.

When assessing the potential cost of the iBOT™ Mobility System, it is important to note that the device's functions have the potential to reduce or eliminate other costs to the beneficiary, whether or not the Medicare program would otherwise cover these costs. For instance, the iBOT™ Mobility System potentially eliminates the need for home modifications such as ramps and other alterations in the home to make a person with a mobility impairment more functional.[63] It also potentially contributes to the ability of appropriate beneficiaries to return to work. The iBOT™ Mobility System has the potential to reduce the need for many home modifications. The 4-Wheel and Stair functions reduce the need for ramps for entry and exit to the home and/or single steps between levels in a home. The Stair function mitigates the need for a chair lift to gain access to another floor of a house. The Balance function and the seat elevation offered by the 4-Wheel function allow for increased participation in and performance of MRADLs such as cooking, cleaning, and grooming that might otherwise require the help of an assistant or be managed in an unsafe or precarious manner.

(e) *Payment Considerations:* While not typically a component of the NCD process, CMS should give consideration in this coverage determination to the negative consequences of classifying the iBOT™ Mobility System as a power wheelchair. Although power wheelchairs are paid under the Capped Rental payment category, under current Medicare law, a supplier must offer the beneficiary the option to purchase the item at the time the supplier furnishes the power wheelchair. This differs from other DME paid under the Capped Rental category which requires that the beneficiary rent the device for 10 months prior to being offered the option to purchase it.

In order to accurately identify those users who will most benefit from the iBOT™ Mobility System, Independence Technology intends to make the device available on a rental basis. This will permit beneficiaries that medically qualify for the device to test the device in their own home environment on a rental basis prior to making the decision to purchase the iBOT™ Mobility System.

Should CMS consider the iBOT™ Mobility System as a power wheelchair, Independence Technology will be required to offer Medicare beneficiaries the option to purchase immediately upon taking delivery of the device. This may have the

[63] In a study by Harrison and Kuric, subjects with SCI identified ramps, wider doors and wheelchair lifts as equipment that would make their homes completely accessible. People who had assistance available or who lived in wheelchair-accessible homes were more likely to use their wheelchair. However, people with lower income levels were less likely to have their homes modified.

unintended consequence of increasing the number of Medicare purchases of the iBOT™ Mobility System for beneficiaries who, in the long term, do not take full advantage of the device's capabilities. Recognition of IBMS devices (including the iBOT™ Mobility System) as a new type of covered DME device—along with a dedicated, unique HCPCS billing code—would support differentiation of these devices from traditional power wheelchairs, thereby permitting IBMSs to be paid under the traditional Capped Rental payment category.

VI. GENERAL INTENDED USE AND PURPOSE OF USE SPECIFIC TO MEDICARE BENEFICIARIES

As already stated, the iBOT™ Mobility System is clearly not appropriate for every Medicare beneficiary with a mobility impairment. Based on a number of both clinical and non-clinical factors, we envision a relatively small subset of Medicare beneficiaries who would ultimately receive the iBOT™ Mobility System. Therefore, we feel it important that we partner with Medicare to arrive at reasonable coverage criteria that meets the legitimate needs of beneficiaries. The development of specific coverage criteria will also be required in order to ensure that the iBOT™ Mobility System is provided only to those beneficiaries who require its enhanced functionality and can take maximum advantage of it.

A. Intended Use Specific to Medicare Beneficiaries

(i) Balancing the Benefit with the Need: A Look at Specific Patient Populations

Although many long-term wheelchair users could *benefit* from specific features of the iBOT™ Mobility System, some will not have sufficient physical or cognitive function to operate the device. See, Section IV, G (i). Others will find it too heavy, restrictive, or bulky for their daily needs. Still others will shy away from the device's reliance on technology. However, there *is* a subset of existing and future Medicare wheelchair users who could literally transform their lives given access to the iBOT™ Mobility System. *These beneficiaries include both qualified power and qualified manual wheelchair users* who, with a mobility device which provides the function enabling capabilities offered by the iBOT™ Mobility System, would be able to either perform or meaningfully increase their participation in MRADLs and other activities in and around the home. In addition to all activities in the home setting, this includes participation in family and community activities, and where appropriate, return to employment or educational endeavors.

Medicare currently recognizes the importance of participation in such activities, both inside and outside the home, through specific references in the final NCD for MAE as well as within the coverage policy for POVs. The final NCD for MAE specifically adopted a "function-based determination of medical necessity." (See, Appendix L; NCD for MAE, p. 4 of 18.) According to the final NCD, this determination "might consider the beneficiaries' inability to safely accomplish activities of daily living such as toileting, feeding, dressing, grooming and bathing with or without the use of mobility equipment, such as a wheelchair." With respect to POVs, the coverage policy indicates that "these vehicles have been appropriately used in the home setting for vocational rehabilitation and to improve the ability of chronically disabled persons to cope with normal domestic, vocational and social activities."[64] By providing coverage of the iBOT™ Mobility System, Medicare will provide access to a device that has the potential to dramatically impact beneficiaries' ability to achieve and surpass these goals of daily living, whereas, without access to the device, they simply would not be able to accomplish MRADLs independently.

[64] Medicare Coverage Issues Manual § 60-5.

(ii) Summary of the Clinical Studies' Findings

Independence Technology conducted a number of studies in support of its PMA submission to the FDA as a Class III medical device. While Section VI of this NCD request provides an in-depth discussion of the results of these studies, the following offers a summary of the results as the basis for segmentation of Medicare beneficiaries that would benefit most from the iBOT™ Mobility System.

Controlled Environment Study ("Controlled Environment")	Real World Community Driving Test ("Real World")
Subjects in this study used the device for a short period of time in a highly controlled setting. Although somewhat limited in scope, this study of 96 wheelchair riders characterized/quantified current functional mobility using the subjects' own mobility devices and compared that level of mobility when using the iBOT™ Mobility System. The findings validate clinical practice that manual wheelchair riders who are able to propel in a "wheelie" position enjoy the highest level of independence, while stairs still present a mobility barrier to even the most skillful riders. In the iBOT™ Mobility System, ALL subjects, demonstrated a higher level of functional independence.	Subjects in this study used the device for two weeks in their home and community environment. This 20-patient study is useful for estimating the proportion of likely users who would gain functional independence in common daily tasks (*e.g.*, climbing stairs, reaching high areas, negotiating curbs). The study also examines the physical exertion required to conduct daily activities when using the iBOT™ Mobility System as compared to using the subject's own device and the level of difficulty in performing specific, self-identified tasks.

Three of the major findings of these studies include:

1) All subjects (that possessed the necessary skills and abilities to safely operate the device) were able to demonstrate functional improvement when using the iBOT™ Mobility System as compared to their current device.

2) Half of all participants could achieve full functionality, including independent stair climbing. Fifty-seven percent (57%) of Controlled Environment and fifty percent (50%) of Real World patients demonstrated the necessary strength and control of both arms and trunk muscles and were able to independently operate all functions of the device. These functions included balance, reach, manipulation of objects and the ability to move about at a standing-eye level. Other functions included the ability to climb curbs and other obstacles, maneuver in confined spaces, travel across a wide range of variable surfaces including steep inclines/declines, traverse flat, hard surfaces, and independently climb stairs.

3) The iBOT™ Mobility System restores functions previously unattainable by even skilled wheelchair users (those able to propel in a "wheelie" position). During the Real World study, all subjects were able to independently retrieve an object from a high shelf in the iBOT™ Mobility System. For seventy percent (70%) of study patients, this was an impossible task to perform independently, prior to the iBOT™ Mobility System.

(iii) Congressionally Mandated Pilot Study

In addition to the two studies described above, the Department of Veterans Affairs conducted a congressionally mandated pilot study in 2001 to assess the potential impact of the iBOT™ Mobility System on people with mobility impairments in the workplace. Four men with traumatic spinal cord injuries with a mean age of 58, two of whom had tetraplegia and two of whom had paraplegia, were the subjects in the study. All of the subjects were employed in an office setting and used manual wheelchairs. The study assessed the ability of each of the subjects to perform a number of activities within the office environment, as well as to conduct business outside of the office. The study concluded that "The subjects were unanimous in their recommendation that the Veterans Health Administration ("VHA") should provide the iBOT™ Mobility System to veterans."[65] The subjects suggested that the iBOT™ Mobility System could improve integration in the workplace and work performance. The two manual wheelchair users with tetraplegia noted the greatest improvement in functional capacity both inside and outside of the work environment. (See, Appendix M for full study details.)

Based on the results of these studies, the following describes which users Independence Technology believes would most benefit from the iBOT™ Mobility System, examining both power and manual users.

(iv) Power Wheelchair Users

Based on FDA clinical trial results, functional restoration using the iBOT™ Mobility System was most significant for those currently using power devices. Current power chair or scooter users who, in the iBOT™ Mobility System, were able to perform stair climbing independently, achieved a significant increase in functional independence. However, because most power mobility users have limited upper extremity function, less than one-third of power wheelchair users studied were able to independently climb stairs.[66] Therefore, although a limited number of beneficiaries using power devices would be able to fully operate the iBOT™ Mobility System independently, those who can fully operate the iBOT™ Mobility System independently demonstrate the greatest clinical improvement and should be strongly considered for Medicare coverage of the iBOT™ Mobility System.

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[65] Rory A. Cooper, et al. Assessment of a Prototype Advanced Mobility Device in the Work Environment of Veterans with Spinal Cord Injury, 14.

[66] Twenty-eight percent of power users enrolled in the Controlled Environment study and 33 percent of those enrolled in the Real World study were able to perform stair climbing independently.

(v) Manual Wheelchair Users: Imminent Risk of Secondary Injury

The iBOT™ Mobility System should be available to two different segments of the manual wheelchair population. The first segment is comprised of skilled manual wheelchair users who are presently encountering, or at imminent risk of, significant secondary injury due to long-term manual wheelchair use. The second segment is comprised of unskilled manual wheelchair users, those persons who are able to self-propel their wheelchair, but unable to propel in a "wheelie" position. The inability of a wheelchair user to propel in a "wheelie" position is the clinical hallmark of a low functioning manual wheelchair rider.

Currently, the Medicare program limits access to power mobility devices to only those beneficiaries who are unable to operate a manual device. However, clinical studies have shown that the repetitive motion and unnatural movement inherent in prolonged manual wheelchair use is a major factor in the high incidence of secondary injuries to the upper extremities among long-term manual wheelchair users.[67] These studies have demonstrated that:

- Due to micro-injury caused by the repetitive motions required to propel a manual wheelchair, long-term manual wheelchair use causes various injuries to the upper extremities. These injuries include rotator cuff tears, lateral epicondylitis, cubital tunnel and carpal tunnel neuropathies and are described in the literature as "overuse pathology."[68] Upper limb joint and nerve degeneration among manual wheelchair users is described as being "astonishingly common." Studies show that the prevalence of carpal tunnel syndrome and shoulder injury is between 30 percent and 70 percent among long-term manual wheelchair users."[69] Such injuries often result in ongoing medical treatment and/or surgical intervention with significant rehabilitation requirements and attendant costs.

- Long-term manual wheelchair use causes pain in the upper extremities. Pain prevalence among paraplegics has been documented as follows: shoulder pain - 39%, elbow - 31%, and wrist/hand 40%.[70] Studies of patients with spinal cord injury report: shoulder pain - 71%, wrist pain - 53%, hand pain - 43%, and elbow pain - 35%.[71]

- A direct correlation exists between the duration of manual wheelchair use and the onset of upper limb injury and pain caused by overuse pathology. The incidence of injuries to the upper limbs among manual wheelchair users, therefore, is both relatively predictable and avoidable. Studies have shown that "One-third [of study participants] had at least

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[67] A.M. Koontz et al. *Propulsion Work and Power Differences in Wheelchair Users with Greater Evidence of Shoulder Pathology at Follow-Up*, Submitted Proceedings RESNA 2002 Annual Conference (June 2002).

[68] Rory A. Cooper et al. *Research on Physical Activity and Health Among People with Disabilities: A Consensus Statement*, 36(2) J. REHABIL. RES. DEV. 142-54 (1999).

[69] Rory A. Cooper et al. *On the Lighter Side*, 3(1) ADVANCE™ FOR PROVIDERS OF POST ACUTE CARE 71-73 (2000).

[70] W.E. Pentland & L.T. Twomey. *Upper limb function in persons with long term paraplegia and implications for independence: Part I*, 32 PARAPLEGIA 211-18 (1994).

[71] M. Dalyan et al. *Upper extremity pain after spinal cord injury*, 37(3) SPINAL CORD 191-95 (1999).

one attack of cervico-brachial pain within one year [of manual wheelchair use]. The frequency [and] duration of the attack tending to increase as time passes." After ten years, 54% [of study participants] had cervico-brachial pain.[72]

- People at greater risk of upper limb injury and pain secondary to prolonged manual wheelchair use include those whose extremities are already compromised by upper limb weakness or muscle imbalance caused by primary disabling conditions such as tetraplegia[73], poliomyelitis, Cardiovascular disease (CVD[74]), severe chronic obstructive pulmonary disease[75], Multiple Sclerosis, and other neurological disorders.[76] In addition, studies have demonstrated (e.g., through MRI analysis) that women are at greater risk of such secondary injury.[77]

Accordingly, the clinical data supports prescriptions of power mobility for individuals with a high risk of upper limb pain and injury secondary to long-term propelling of a manual wheelchair. The current, non-surgical option for the treatment of upper extremity impairment is to recommend the use of a power wheelchair to conserve and preserve the functioning of the joints. However, the use of a traditional power wheelchair introduces a significant drop in overall functional independence. The previously skilled manual wheelchair rider is unable to negotiate a curb or get through soft surfaces in a power mobility device. When the wheelchair casters become stuck, the rider is no longer able to just "pop a wheelie" to free-up the casters. Traditional power wheelchairs dramatically restrict the rider's options in terms of requiring assistance from others. When in a manual wheelchair, a rider can often be assisted by another person to ascend a step or two. In a power wheelchair, however, as many as four people may be needed to ascend even one step.

Although the iBOT™ Mobility System is a "powered" mobility device, the results of the clinical trials indicated that there was no reduction in functional independence as was seen with power wheelchairs. In fact, for subjects recommended as candidates for use of the iBOT™ Mobility System, the device increased functional independence, rather than having the "traditional" negative impact of power wheelchairs (*i.e.,* reduced ability to negotiate curbs and soft surfaces). The iBOT™ Mobility System provides a treatment option—and we recommend that Medicare cover this option—for Medicare beneficiaries whose environment does not accommodate traditional mobility devices and which conserves and preserves the upper extremities of long term manual wheelchair users at imminent risk of secondary injury, without the functional

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[72] P.J.R. Nichols et al. *Wheelchair User's Shoulder?* 11 SCAND. J. REHABIL. MED. 29-32 (1979).

[73] Kathleen Curtis et al. *Shoulder Pain in Wheelchair Users with Tetraplegia and Paraplegia*, 80 ARCH. PHYS. MED. REHABIL. 453-57 (1999).

[74] Cooper, *supra* note 68, at 146.

[75] Department of Veterans Affairs, Handbook 1173.6, *at* http://www1.va.gov/vhapublications/publications.cfm?pub=2.

[76] Pentland, *supra* note 70.

[77] Lin Ma et al. *Gender difference in the segmental power and energy of manual wheelchair propulsion*, SUBMITTED PROCEEDINGS RESNA 2002 ANNUAL CONFERENCE (June 2002).

compromises currently experienced by power wheelchair riders.[78] Such a change from current policy would very likely decrease the incidence and prevalence of secondary injury, which oftentimes manifests itself in costly medical/surgical corrective interventions.

(vi) Manual Wheelchair Users: The "Wheelie" Standard

The second segment of manual wheelchair users who would be most appropriately provided with access to the function-enabling capabilities of the iBOT™ Mobility System is comprised of "low functioning" users. We propose to utilize the ability to achieve and travel in the "wheelie" position as a standard to assess whether a manual wheelchair user is considered low functioning. The ability of manual wheelchair users to independently balance and travel in the "wheelie" position is viewed as the current benchmark for maximum functional mobility for those who use wheelchairs,[79] including the ability to independently climb curbs and negotiate variable surfaces in a wheelie position.

Because these users have good strength and control of arm and trunk muscles, most of these "skilled" manual users are able to fully operate the iBOT™ Mobility System independently, including performance of independent stair climbing and other functions.[80] Although the mean functional scores for all successful candidates were higher when using the iBOT™ Mobility System, these skilled users demonstrated the smallest incremental gain in functional mobility improvement as compared to their own devices. These same users demonstrated relatively small functional improvement gains when compared to the much greater incremental gains of current power device users or manual users who were unable to travel in the wheelie position.

In the clinical studies performed by Independence Technology with the iBOT™ Mobility System, the change in "everyday" mobility of low functioning manual wheelchair users was demonstrated to be significant. While able to independently propel a manual wheelchair, these low functioning users (unable to propel in a wheelie position), encounter a large number of

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[78] This would be consistent with the VA's coverage criteria for powered mobility and the iBOT™ Mobility System. In its Clinical Practice Recommendation ("CPR") for power mobility, the VA states that power devices are appropriate for manual users under certain circumstances. In the CPR for the iBOT™ Mobility System, the VA indicates that the beneficiary should have a need for stair-climbing. (See, Appendix H for VA iBOT™ Mobility System coverage policy.)

[79] PENN STATE UNIVERSITY COLLEGE OF MEDICINE, *Levels of Spinal Cord Injury* (2001) (where the goal of a person with a C8 spinal cord injury would be "Independent in "wheelie" and negotiating 2 inch door sill, independent in negotiating a 4 inch curb); UNIVERSITY OF CENTRAL ARKANSAS, DEPARTMENT OF PHYSICAL THERAPY, *Neuromuscular Complex* (2003) (stating that a person with a C-8 to a T-1 spinal cord injury should have the functional capability to perform independent wheelies and that "[t]he wheelie is a basic skill for anyone who hopes to become a fully independent wheelchair user"); L. Kirby et al., *The Wheelchair Skills Test: A Pilot Study of a New Outcome Measure*, 83(1) ARCH. PHYS. MED. REHABIL. 10-18 (2002) (referring to performing a wheelie as one of the most difficult skills for a wheelchair user); Matthew McInnes et al., *The Contribution of Vision to Wheelie Balance*, 81(8) ARCH. PHYS. MED. REHABIL. 1081-84 (2000) ("The ability to maintain balance while in the wheelie position is essential to the safe and effective performance of such wheelie-related skills" as ascending and descending curbs, descending steep inclines, crossing soft or uneven surfaces, and turning in narrow spaces.

[80] Eighty-eight percent of "skilled" manual users were able to independently operate all functions of the iBOT™ including climbing stairs in the Real World Community Driving Test. In the Controlled Environment Study, 100 percent of "skilled" manual users were able to independently operate all functions of the device including climbing stairs.

everyday mobility obstacles. Something as seemingly simple as a door threshold in an old New England home presented an insurmountable object to some low functioning riders. These riders were unable to climb obstacles, curbs or push through soft surfaces, without the assistance of another person. Independent mobility was truly limited from point A to point B, providing A and B were on a flat level surface. For these riders, the ability to figuratively "pop a wheelie" by using the varied functions of the iBOT™ Mobility System was a dramatic improvement in functional independence.

As already stated, study results demonstrate that manual users who do not possess the skill of "popping" and maintaining a "wheelie," nor the physical abilities to achieve this skill independently, inherently have the greatest potential to increase their functional capacity using the iBOT™ Mobility System. In both the Controlled Environment and Real World studies, functional restoration when using the iBOT™ Mobility System was most dramatic for manual wheelchair users who were unable to operate a wheelchair manually in the "wheelie" position.[81] However, these same users had more limited upper extremity function and few were able to generate enough leverage to independently climb stairs. Therefore, a limited number of manual users unable to operate their own device in the wheelie position were able to fully operate the iBOT™ Mobility System independently (to include independent stair climbing). Those who can fully operate the iBOT™ Mobility System independently demonstrate the greatest clinical/functional improvement.

Notwithstanding the fact that current Medicare coverage policies currently exclude all manual wheelchair users from coverage for power devices, ***we recommend that CMS consider a subset of manual wheelchair users for coverage of the iBOT™ Mobility System, including those who are unable to propel a manual wheelchair in a wheelie position, or are at imminent risk of upper extremity injury secondary to long-term manual wheelchair use.***

B. Purpose of Use – Ensuring Appropriate Access

Medicare has previously considered the physician's prescription and the Certificate of Medical Necessity as adequate for determining necessity of a mobility device for the treatment of an injury or malformed body member, assuming documentation in the patient's file supports this determination. With increased efforts to combat inappropriate prescriptions for unnecessary mobility devices, the unique process for obtaining the iBOT™ Mobility System, as described in Section IV, F of this NCD, will identify those beneficiaries who are capable of utilizing all of the functions of the device and, thereby, would benefit most from these features. The VA's prescription protocol (included in their Clinical Practice Recommendation) demonstrates how one payer has incorporated the Independence Technology business model into its own review procedures to ensure appropriate access. (See, Appendix J.)

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[81] With one exception, all such subjects (manual chair users unable to perform a wheelie) in the Real World Study were unable to climb curbs (up and down), unable to climb a one step entrance/exit, and unable to negotiate soft surfaces or uneven surfaces independently when using their own device. The lone exception was a subject who could climb a one step entrance/exit with significant exertion. With one exception, when using the iBOT™ Mobility System all subjects were able to negotiate all these environments independently with minimal effort. The lone exception was a subject who decided to use the Stair Function on the one step exit; this subject could only use stair function with an assistant.

C. Consistency Between the New NCD for Mobility Assistance Equipment and Coverage of the iBOT™ Mobility System

The final National Coverage Determination for MAE is consistent with coverage of the iBOT™ Mobility System for a select group of Medicare beneficiaries, namely those beneficiaries whose typical environment does not support the use of wheelchairs, including scooters/POVs. The NCD's "Clinical Criteria for MAE Coverage," along with the related algorithm, asks a series of questions using a graduated process that address the mobility needs of beneficiaries. Before obtaining access to *any* wheeled mobility device, a Medicare beneficiary must satisfy question number six which reads as follows:

> "6. Does the beneficiary's typical environment support the use of wheelchairs including 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 physical layout, surfaces, and obstacles, which may render mobility equipment unusable in the beneficiary's home."

See, National Coverage Determination for MAE, Appendix L, and Related Algorithm.

The answer to question number six results in one of two potential outcomes. The beneficiary will either progress to the next set of questions related to the beneficiary's ability to use a manual wheelchair, or, coverage for a wheeled mobility device will be denied as not medically necessary. This will likely be because the beneficiary's environment presents obstacles to mobility through the use of a traditional mobility device including manual wheelchairs, power wheelchairs or scooters/POVs. What such a beneficiary will do in this instance is not clear, but it appears that such a beneficiary will not be eligible for *any* mobility device whatsoever.

The iBOT™ Mobility System is ideally suited to accommodate this situation. The device is specifically designed to overcome the environmental barriers of a home's physical layout, variable surfaces, and obstacles that would otherwise render traditional mobility devices unusable. ***Therefore, we propose, through this NCD request, to amend the current Clinical Criteria for MAE Coverage (as well as the related algorithm) and augment it with an additional set of questions (and a related amended algorithm) that seeks to meet the needs of beneficiaries who would otherwise be denied access to any mobility device under the existing coverage policy***. See, Appendix N, which is comprised of an amended algorithm.

(i) Separate Coverage Criteria are Required for the iBOT™ Mobility System

The creation of a coverage policy, including patient selection criteria, specific to Interactive Balancing Mobility Systems (and inclusive of the iBOT™ Mobility System) will ensure that the prescribed technology is medically necessary and appropriate for the beneficiaries who receive it. Based on the unique and unprecedented functional capabilities that the iBOT™ Mobility System provides and the physical, perceptual and cognitive abilities required to safely operate

the device, the technology will require new coverage and documentation standards. Because the device provides an entire range of functions beyond those of current mobility devices, and will only be available once it is determined that a particular beneficiary's typical environment cannot accommodate a traditional mobility device, the application of current coverage policies for power devices to the iBOT™ Mobility System would not be clinically appropriate. The clinical study protocol and FDA labeling provide a better basis for appropriate criteria.

Our suggested coverage criteria seek to identify Medicare beneficiaries who have the greatest potential to improve their ability to perform or participate in mobility related activities of daily living in the home environment through the use of an IBMS (represented by the iBOT™ Mobility System). The criteria target a relatively small subset of beneficiaries, as described in detail below.

(ii) The Coverage Determination Process for the iBOT™ Mobility System

The coverage determination process for the iBOT™ Mobility System would begin with a negative answer to question number six (6) of the NCD for MAE. This would mean that a finding would have to be made that the typical environment of the beneficiary does not support the use of either manual or power wheelchairs or scooters/POVs due to "obstacles, surfaces or the physical layout" of the beneficiary's home. (See, Appendix L; NCD for MAE and attached coverage algorithm.) These traditional mobility devices would be essentially unusable in this instance. Rather than receiving no treatment as a result of this inquiry, a beneficiary in this position would then be asked the following series of questions:

Question 1

Would an Interactive Balancing Mobility System (IBMS) (e.g., the iBOT™ Mobility System) enable the beneficiary to increase participation in or performance of MRADLs in the home environment in a safe manner?

This question could be answered through the use of Independence Technology's Product Qualification Survey ("PQS") and its Medical Clearance Form (or similar assessment instruments that CMS may issue) (See, Appendices C and D, respectively.). Two common contraindications of the iBOT™ Mobility System that lead to denials at this point are (1) if the consumer weighs more than 250 pounds and (2) the beneficiary requires a tilt and recline feature for activities of daily living and/or pressure relief. Assuming the beneficiary qualifies under these assessment tools and is motivated to continue the process, a test drive would be scheduled in order for the beneficiary to experience the various functions of the iBOT™ Mobility System and assess his or her comfort level with the operation of the device. If the beneficiary either does not qualify or is not interested in pursuing coverage of the iBOT™ Mobility System at this point, mobility device coverage would be denied as not medically necessary for the beneficiary, consistent with the current NCD for MAE.

High Functioning Power Wheelchair Users

However, if the beneficiary qualifies for coverage under these initial screening tools and is motivated to continue the coverage process, the beneficiary would be asked the following question:

Question 2

Is the beneficiary able to self-propel a manual wheelchair?

If the answer to this question is "no," then a secondary question would be asked:

Question 2(a)

Is the beneficiary able to operate a joy stick?

If the beneficiary is not able to operate a joy stick, then the iBOT™ Mobility System would not be reasonable and necessary for the beneficiary because operation of a joy stick is integral to the safe operation of the device. However, if the beneficiary *is* able to operate a joy stick, then the beneficiary would need to demonstrate whether he or she could safely operate the device through passage of a detailed assessment. Independence Technology has developed a "Functional Capacity Evaluation" or "FCE" that is performed by an independent clinician and assesses the beneficiary's ability to maneuver in the device, use the joy stick, respond to obstacles, and generally operate the device in a safe and effective manner. If the beneficiary passes this final assessment, coverage for an iBOT™ Mobility System would be approved. A typical scenario where such coverage might occur would be the case of a newly injured, high functioning quadriplegic whose typical environment is not equipped for wheelchair access.

Low Functioning Manual Users

Based on the clinical studies, high functioning power wheelchair users are not the only subgroup that can obtain maximum benefit from the multiple functions of the iBOT™ Mobility System. The clinical studies indicate that the device also meets the unique needs of low functioning manual wheelchair users. Therefore, the proposed algorithm asks a series of additional questions if the answer to number two (2) above is "yes," *i.e.,* the beneficiary *is* able to self-propel a manual wheelchair. Such a beneficiary would then be asked:

Question 3

Is the beneficiary able to self-propel a manual wheelchair in a "wheelie" position?

If the answer to this question is "no," then this is a clinical indication that the beneficiary is a low functioning manual wheelchair user who, given the obstacles in his or her typical environment, would be a candidate for iBOT™ Mobility System coverage. Like the beneficiary who is able to utilize a joy stick above, this beneficiary would be required to undergo the Functional Capacity Evaluation administered by an independent clinician and, if he or she passed this assessment,

coverage for the iBOT™ Mobility System would be granted. If the beneficiary did not pass the assessment, coverage for the iBOT™ Mobility System, as well as any mobility device, would be denied, consistent with the current NCD for MAE.

If the beneficiary *is* able to self-propel a manual wheelchair in a wheelie position, this indicates the person is a skilled manual wheelchair user. In this instance, the beneficiary would be asked the following question:

Question 4

Is the beneficiary at imminent risk of secondary injury due to manual wheelchair use?

The clinical literature clearly demonstrates the prevalence and risk of upper extremity injury secondary to manual wheelchair use, particularly in patients with upper extremity weakness or muscle imbalance (such as tetraplegia, poliomyelitis, Multiple Sclerosis, and other neurological disorders). See, Section VI, A (v). If the answer to this question is "no," *i.e.,* the beneficiary is not at imminent risk of secondary injury, then coverage for the iBOT™ Mobility System (as well as any mobility device) would be denied as not medically necessary, consistent with the current NCD for MAE.

However, if the beneficiary *is* at imminent risk of secondary injury, most likely due to a clinical condition that has compromised the strength of the upper limbs, the beneficiary would be eligible to undergo the assessment provided by an independent clinician. If the beneficiary failed the assessment, coverage for the iBOT™ Mobility System, as well as any other mobility device, would be denied. If the beneficiary passed the assessment, coverage for an iBOT™ Mobility System would be granted. In this manner, a beneficiary who has negotiated his or her typical environment for years in a manual wheelchair will be able to conserve and preserve his or her upper extremity function while not encountering the typical restrictions in access that standard power wheelchairs commonly bring (*e.g.*, lack of maneuverability in tight spaces, inability to traverse single steps to access different levels of the home, etc.).

VII. DISCUSSION OF EVIDENCE

A. Compilation of Evidence

Clinical trials were conducted to demonstrate how the iBOT™ Mobility System restores functionality to current wheelchair users, particularly as compared to existing devices. To support the FDA's assessment of this new technology, two primary clinical trials were conducted—one in a controlled environment and another in the "real world." Gains in functional independence and improvement in the Controlled Environment Study were substantially validated by the conclusions reached in the Real World comparison.

The clinical trial was a single center, prospective, balanced open label evaluation that utilized participants as their own control. Twenty-nine (29) subjects were enrolled. Twenty (20) subjects completed the study and nine subjects did not (two failed assessment, three withdrew from the study, and four were terminated by the investigators). The initial two subjects (considered skilled manual wheelchair users) completed the Pilot Trial. Eighteen (18) subjects (6 skilled manual wheelchair users, 6 slow manual wheelchair users, and 6 power wheelchair users) completed the Real World Trial. Each Real World Trial subject participated in the study for four weeks; two weeks in his or her own device and two weeks in the investigational device. Pilot Trial participants used each device for one week. Pilot Trial participants and clinical investigators trained by following the iBOT™ Mobility System Training Program.

Subjects were required to maintain a diary of their activities based on six-point scoring system.

Rating	Scoring System
0 = Not Tested	Task not tested because function specific restriction or subject declines or requires more than one assist to complete
1 = Assisted with Maximum Exertion	Subject is able to complete the task with physical assistance and maximum exertion by the assistant.
2 = Assisted with Moderate Exertion	Subject is able to complete the task with physical assistance and moderate exertion by the assistant.
3 = Assisted with Minimum Exertion	Subject is able to complete the task with physical assistance and minimum exertion by the assistance.
4 = Independent with Maximum Exertion	Subject requires maximum exertion without physical assistance to complete the task.
5 = Independent with Moderate Exertion	Subject requires moderate exertion without physical assistance to complete the task.
6 = Independent with Minimum Exertion	Subject is able to independently complete the task with minimal to no exertion without physical assistance.

(i) Primary Inclusion Criteria

1. Subjects were between 19-80 years of age
2. Subjects used one of the following mobility aides: a manual wheelchair, a power wheelchair with a hand-operated joystick control, or a scooter as their primary mobility device. Additionally, subjects could be defined as:

    a. Skilled manual wheelchair user; identified as a subject who routinely propels faster than walking speed and is able to travel in a "wheelie" position for 10 feet.
    b. Slow manual wheelchair user; identified as a subject who self propels at walking speed or slower and/or is unable to self propel or travel in a "wheelie" position for 10 feet.
    c. Power (including scooter) wheelchair; identified as a subject who is using a power wheeled mobility device as his/her primary means of mobility outside their home.

(ii) Primary Exclusion Criteria

1. The subject weighed more than 250 pounds.
2. The subject was unable to use a wheelchair seat between 14" and 20" wide.
3. The subject was not able to bend his/her knees and hips such that the back and feet fit on standard rests. For people with an amputation(s), this did not apply and these subjects were not excluded from the study.
4. The subject did not have sufficient function of at least one upper extremity to dial a push button telephone and operate a hand-operated joystick.
5. The subjects' postural supports used in their own device were not compatible/comparable with the postural supports of the iBOT™ Mobility System.
6. The subject experienced an impaired level of consciousness or had a seizure in the last 90 days.
7. Subjects who required use of a tilt or recline seating system.
8. Subjects who required assisted mechanical ventilation.
9. Subjects who were unable to use their own cushion due to sizing or other reasons if they had prior pelvic/thigh region decubitus ulceration problems.
10. Subjects who had an active pelvic/thigh region decubitus ulceration.

(iii) Function Specific Exclusion Criteria

11. "Solo" Stair Climbing Function:
    a. Cardiac Risks: The subject reported a history of cardiac impairments that limited his/her ability to perform ordinary physical activity.

b. Pulmonary Risks: The subject reported a history of pulmonary impairments that limited his/her ability to perform ordinary physical activity.
c. Fracture Risks: The subject was at a high risk for fracture or spinal instability, secondary to unstable hip or spinal compression a result of: severe osteopenia, osteogenesis imperfecta, and/or spinal metastatic bone cancer.

12. "Curb Climbing" 4-Wheel Function:
    a. Fracture Risks: The subject who avoided curb-climbing activities, and was at a high risk for fracture or spinal instability secondary to unstable hip, or spinal compression as result of: severe osteopenia, osteogenesis imperfecta, and/or spinal metastatic bone cancer. Until or unless cleared by a physician, no curb climbing activities were tested.

13. Balance Function:
    a. Fracture Risks: The subject was at a high risk for fracture or spinal instability, secondary to unstable hip, or spinal compression as a result of: severe osteopenia, osteogenesis imperfecta, and/or spinal metastatic bone cancer. Unless cleared by a physician, Balance Function was deactivated.

(iv) Demographics

There were 16 male and 4 female subjects with ages ranging from 27 to 67 years (mean age was 43.7 years; medican age was 42.5 years). Weight ranged from 81-230 pounds (mean weight was 165 pounds; median weight was 160 pounds). Medical conditions included spinal cord injury (SCI) paraplegia (9 subjects), SCI tetraplegia (4 subjects), neuromuscular conditions (4 subjects), amputee (2 subjects), SCI tetraplegia plus amputee (1 subject).

(v) Utilization Data

Data Logger Distributions

Parameter	Units	Training Days	Real World	Test Day	Totals
Master Odometer	km	96.2	329.7	77.0	502.9
Balance Odometer	km	19.1	53.8	12.4	84.3
Enhanced Odometer	km	28.9	81.7	24.8	135.4
Standard Odometer	km	46.1	191.2	39.2	276.5
Cluster Odometer	rotations	3112	1888	805	5805
Total Time in Active Functions	hours	249.2	1026.1	164.9	1440.2
Balance Hour Meter	hours	29.4	94.7	13.9	138.0
Enhanced Hour Meter	hours	51.5	142.8	28.0	222.3
Stair Hour Meter	hours	23.6	4.0	3.9	31.5
Standard Hour Meter	hours	144.5	784.6	119.0	1048.1
Remote Hour Meter	hours	1.2	3.5	1.2	5.9
Sleep Hour Meter	hours	89.0	356.1	38.9	484.0
Seat Height Actuator Hour Meter	hours	1.9	5.7	0.9	8.5
Stair Entry Count	count	772	141	142	1055
Sleep Entry Count	count	665	1357	183	2205
Controller Failure Count	count	0	4	1	5

(vi) Safety Data

The safety of the iBOT™ Mobility System was established by comparing the rate of adverse events occurring in the investigational device and in the subjects own devices.

Event Type	IBOT™ Mobility System	Own Device
Device Related – Medical Treatment at Hospital	0	0
Not Device Related – Medical Treatment at Home	2	0
Not Device Related – Medical Treatment at Hospital	0	4
Fails Not Requiring Medical Treatment	3	2

There were two adverse events associated with the use of the product. The first was during the assessment in the IBOT™ Mobility System when the subject pinched his mid-forearm between the User Control Panel (UCP) and the armrest, resulting in a small bruise. A forearm pad was utilized to prevent further problems; no other medical treatment was provided. A second subject was driving in Balance Function. The subject observed a tree cutout in the sidewalk and turned right to avoid the tree. He turned too far to the right and the right wheel struck a 5 inch curb, he quickly attempted to turn the device to the left while the right wheel attempted to climb the curb. This caused lateral instability and the device tipped and fell to the left. Passersby lifted the subject in the device to an upright position, Recovery Mode was activated, and the subject continued on to work. The subject received a bruise on his leg that did not require treatment.

(vii) Effectiveness Data

The primary efficacy variable in this study was the score subject obtained on a Community Driving Test consisting of 15 tasks that one would encounter in everyday life. Subjects' scores using the iBOT™ Mobility System were compared to scores using their own mobility devices.

- All 20 subjects (2 Pilot and 18 Real World subjects) scored higher in the iBOT™ Mobility System than in their own device and showed an improved level of independence ($p<.001$).

- In every task (11 such tasks) in which the Stair Function, the 4-Wheel Function or the Balance Function was utilized, there was an improvement in the subject's scores and level of independence (range from $p<.001$ to $p=.008$).

- As expected, in tasks (4 such tasks) in which Standard Function was utilized, only manual slow users tended to show an improvement in test scores and independence level.

- In general, the iBOT™ Mobility System was more difficult to maneuver indoors (e.g., due to seat height)[82] but provided greater mobility outdoors as compared to the subjects' own mobility devices.

There were some limitations to the study. The primary effectiveness measure (Community Driving Test) did not test the Remote Function. Nor did it test the ability to climb stairs using two railings. However, the subjects were assessed for stair climbing with two railings according to the training protocol in the Delivery Guidebook prior to home and community use. The Balance Function was tested while performing only one task. Seven of the 20 subjects used the Balance Function for less than a total of two hours during the study period, and it is not clear whether any of this usage was outside the training and assessment sessions. Only one of the 20 subjects used the Remote Function and two subjects used the fast speed template.

Configuration	#Subjects N=20
Solo only, 1 & 2 Rails	8
Solo (1 & 2 Rails*) & Stair Assist	2
Solo (2 Rails*) & Stair Assist	2
Stair Assist only	8

[82] With the iBOT™ 3000 Mobility System, which was the subject of these studies, the seat height was higher relative to other types of mobility devices primarily due to the components that enable the device to balance and climb stairs. Some participants in the study had difficulty maneuvering within their homes because they had set up their homes to accommodate their existing wheelchairs. Knowing that the clinical study would not last for more than two weeks, the participants were not as likely to make changes to table heights, etc., as they might be if the iBOT™ Mobility System were their permanent mobility device. On March 15, 2005, the FDA approved generational changes to the iBOT™ Mobility System. The new seat to floor height is close to 4" lower than the previous generation. The particular conclusion reached in this study, therefore, should no longer be valid.

*Although the Community Driving Test did not test stair climbing with 2 railings, subjects were tested during the delivery training and assessment prior to the home and community use phase.

(viii) Mechanical Failures, Computerized Alerts and Technical Difficulties

Twelve of the 20 subjects experienced a total of 22 events that resulted in replacement of one or more component replacements. Nine events occurred with the patients' own devices and 13 events occurred with the iBOT™ Mobility System. None of these device failures resulted in subject injury.

There were three instances where the iBOT™ Mobility System was replaced in its entirety in this study. Each of these could have been handled as a device component replacement, however, replacing the entire device minimized inconvenience to the subject. In one case, there was a battery charging issue in the late evening. Rather than taking time to repair the components (a bent charger port pin) at the subject's home, it was decided to replace the device and let the subject retire for the evening.

In the second case the subject was at a restaurant just prior to the lunch hour when the device was unable to change the seat height as intended by the subject. It was decided to replace the device and not further inconvenience the subject.

In the third case the UCP backlight failed to function during Stair Training. At the conclusion of Stair Training (approximately ½ day) it was decided to have the subject take a different device home rather than have the subject wait while the device was repaired.

In addition to these three occurrences, there were ten (10) other events where one or more iBOT™ Mobility System component replacements were required.

(ix) Computerized Alert and Failure Identification Data

The iBOT™ Mobility System computer software identified the number and types of computerized alert and failure actions experienced during the device usage period (Table 3). The software is designed to identify these events and to respond in a manner intended to prevent or minimize device damage and user injury. For each alert or failure count, the device responded as it was designed. However, these automated actions represent potentially harmful situations, e.g., in two of the five controller failure events, the device fell and the patient's medical condition may have contributed to the fall. These types of data are not available for the users' own mobility devices since they did not have these technical features.

Table 3. Computerized Alert and Failure Identification data

Alert/Failure	Total (count)
Controller Failure	5
Controller Auto 4-Wheel	22
Controller Alert Balance	42
Controller Alert 4-Wheel	3
Controller Alert Stair	80
4-Wheel Off Top of Stair	62
Wheel Motor Hot	4
Cluster Motor Hot	89
Security Password	0
Service Trigger	17

(x) Mechanical/Operational Difficulties

Overall, users experienced more mechanical and operational difficulties with the iBOT™ Mobility System than with their own mobility devices, mainly with the batteries, user control panel and user techniques (Table 4).[83] Users' own mobility devices had more tire problems than experienced with the iBOT™ Mobility System.

Table 4. Mechanical/Operational Difficulties

Mechanical/Operational Difficulty	iBOT™ Mobility System	Own Device
Assist Handle/Backrest	1	1
Battery	18	3
Cluster/Wheel/Caster	7	6
CPU Fault	2	0
Footrest/Armrest	3	2
Modem Cable	3	0
Seating/Seat Height	4	2
Tires	3	7
User Control Panel	5	0
User Technique	11	2
Other	1	2

[83] Due to the generational changes to the iBOT™ Mobility System mentioned in footnote 82 and significant improvements made to the User Control Panel (See, Appendix C for a picture of the UCP), the device now offers improved drive performance, greater reliability, and we anticipate lower maintenance and service costs.

VIII. CONCLUSION

The iBOT™ Mobility System is a transformational mobility device that is worthy of a favorable National Coverage Determination. CMS should cover the iBOT™ Mobility System under the DME benefit. The device clearly meets the four prong definition of DME, including the requirement that the device is primarily medical in nature and is appropriate for use "in the home." The innovative functions of the device should be considered covered DME benefits as compelling analogies exist under current Medicare coverage policies that form the basis for a favorable coverage determination. The iBOT™ Mobility System is reasonable and necessary for a small subset of Medicare beneficiaries, in that the cost of the device is not disproportionate to the value it brings in terms of net health outcomes to specific beneficiaries in need of comprehensive functionality. Because the iBOT™ Mobility System has no equal in terms of integrated functionality within one, portable mobility device, it is a highly stable and safe mobility device which has no less costly alternative for those who require its enhanced functions.

Coverage of the iBOT™ Mobility System should be granted only when the beneficiary's typical environment renders traditional mobility devices unusable and the device will enable or assist the beneficiary to perform or participate in mobility related activities of daily living, consistent with the NCD for MAE. Such beneficiaries should be assessed for coverage of the device based on an algorithmic process that is consistent with the NCD for MAE. This process should seek to identify low functioning manual wheelchair users and high functioning power wheelchair users who need the iBOT™ Mobility System to improve performance of or participation in mobility related activities of daily living.

It is for these reasons that Independence Technology requests CMS to assess this NCD with a recognition that the iBOT™ Mobility System is truly a breakthrough technology deserving of an affirmative coverage decision. We recommend that CMS establish coverage for this new type of mobility device, what we refer to as the "Interactive Balancing Mobility System," represented by the iBOT™ Mobility System. We also suggest that CMS develop specific coverage criteria and documentation requirements for this device under the Medicare DME benefit in order to appropriately control utilization while providing access to this device for those who require its extensive functionality and can benefit the most from it.

We appreciate the opportunity to submit this application and look forward to working with CMS officials to answer any questions that may arise from this NCD request.