ADDENDUM

CLINICAL PRACTICE RECOMMENDATIONS FOR MOTORIZED WHEELED MOBILITY DEVICES: iBOT POWER WHEELCHAIR

I. PURPOSE: The purpose of these clinical practice recommendations is to provide physicians, therapists and other authorized personnel with functional criteria for prescribing an iBOT power wheelchair.

II. BACKGROUND

The Under Secretary for Health directed VHA's Prosthetic and Sensory Aids Service Strategic Healthcare Group (PSAS SHG) to establish a Prosthetic Clinical Management Program (PCMP). The objectives were to coordinate the development of clinical practice recommendations for prosthetic prescription practices and contracting opportunities to assure technology uniformity and ease of access to prosthetic prescriptions and patient care that will lead to valid outcome measures and analysis for research purposes.

The iBOT is a battery-powered wheelchair that relies on a computerized system of sensors, gyroscopes and electric motors to allow indoor and outdoor use on stairs as well as on level and uneven surfaces. It has the potential to improve the quality of life of many people with mobility limitations by 1) enabling them to manage stairs, 2) reach high shelves and 3) hold eyelevel conversations. It can easily be converted from a standard powered wheelchair with four wheels contacting the ground to an elevated powered wheelchair balanced on only two wheels. The iBOT approval by the Food and Drug Administration in August 2003 was based on a review of extensive bench testing and a clinical study by the manufacturer, Independence Technology, a Johnson and Johnson (J&J) company.

Utilizing prescription guidelines provided by J&J, the PSAS SHG, in conjunction with the National Program Director for Physical Medicine and Rehabilitation Service and the Chief Consultant, Spinal Cord Injury and Disorders, initiated pilot studies/training sessions to VA clinical staff at seven VA Medical Centers (Washington, DC; Nashville, TN; Gainesville, FL; Albany, NY; Seattle, WA; Denver, CO; and Buffalo, NY). J&J required the VA clinical staff to receive four days of training before they were allowed to prescribe the

iBOT and the patient to receive two to three days of training to learn how to safely operate the iBOT.

The iBOT power wheelchair has unique features that may be beneficial for some with impaired mobility. There are also limitations and considerations for its use as evidenced by small samples studied by the VA, the Canadian Coordinating Office for Healthcare Technology Assessment and the University of Pittsburgh. The provision of the iBOT will follow clinical criteria identified by the PCM National WorkGroup on Motorized Wheeled Mobility Devices which addresses the iBOT as one multi-functional power wheelchair option.

Each veteran is entitled to an individualized evaluation. The clinician will take into account the veteran's medical diagnoses, prognosis, functional abilities, limitations, goals, and ambitions. Evaluation of mobility will assess musculoskeletal, neuromuscular, pulmonary, and cardiovascular capacities and response, effort, quality and speed of gait (or manual wheelchair propulsion), and overall function. Power mobility is indicated when the veteran demonstrates a clear functional need that cannot or is not likely to be met by conventional rehabilitation or medical interventions and is not otherwise contraindicated. The VA supports the dispensation of power mobility to allow the veteran to access medical care and to accomplish necessary tasks of daily living in ordinary home and community environments such as paved surfaces and mild terrains (low grass, packed sand and gravel, etc.). While recreational needs may be taken into consideration, the VA does not support the dispensation of power mobility solely for recreational purposes.

III. MEDICAL CRITERIA

Prior to being referred to a VA iBOT certified clinician, the veteran must meet the following VA specific and Independence Technology iBOT criteria:

A. VA specific iBOT criteria

- Meets eligibility for a powered wheelchair as specified by Clinical Practice Recommendations for Motorized Wheeled Mobility Devices published September 14, 2004, and approved by Jonathan B. Perlin, MD, PhD, MSHA, FACP, Acting Under Secretary for Health. These clinical practice recommendations can be found at http://vaww1.va.gov/prosthetics
- Has clear functional mobility goals that may be best met by the iBOT
 (alternative power chairs do not meet identified needs satisfactorily,
 i.e., power chair with seat elevation, power chair with standing function,
 power chair designed for extreme environments, etc.).

B. Independence Technology iBOT criteria

- Client weighs less than 250 pounds, including any usual items on chair (cushion, backpack, etc.).
- Fits seat width between 16 inches and 18 inches.
- Fits seat depth between 16 inches and 18 inches.
- Does not have range of motion (ROM) limitations at the hips that preclude the use of standard seat to backrest configurations (maximum 10 degree seat tilt).
- Does not have ROM limitations at the knees, ankles, or feet that preclude use of standard hangers and footrests.
- Has sufficient function of at least one upper limb to dial a push button phone and operate a standard joystick. This will allow operation of basic functions and assisted stair climbing function.
- Has sufficient bilateral upper limb function for independence with stair climbing function or a caregiver is available to provide assistance for the stair climb function or this option is not applicable.
- The client has not experienced a seizure in the last 90 days.
- The client does not require custom seating interventions for postural support or control (i.e., lateral supports, custom back or custom seat configuration).
- Does not require a tilt or recline seating system.
- Does not require mechanical ventilator while using a wheelchair.
- Does not have severe osteoporosis, osteogenisis imperfecta or metastatic bone cancer.
- Cardiac and/or pulmonary conditions have been reviewed and cleared by medical doctor in order to be considered for the stair climbing function.
- Does not have visual, auditory or perceptual impairments sufficient to compromise operation of an iBOT.

IV. PRESCRIPTION PROTOCOL

- A. Local Wheelchair Clinic or equivalent receives a consult for consideration of an iBOT.
- B. The local Wheelchair Clinic evaluates the patient and screens the patient for an iBOT in accordance with this Addendum.
- C. If the local Wheelchair Clinic determines that the patient is a likely candidate for the iBOT, a consult is forwarded to a designated iBOT Training Center in the veteran's Veterans Integrated Service Network (VISN). See Attachment. The iBOT Training Center screens the consult and determines whether or not the patient will receive further consideration for the iBOT.
- D. If the veteran passes the screen, it is the veteran's responsibility to travel

to the designated iBOT Training Center.

- E. The veteran arrives at the iBOT Training Center and is evaluated to determine whether the veteran qualifies for an iBOT. This evaluation may include actually training on the iBOT.
- F. The iBOT training evaluation team recommends dispensation or denial of the iBOT.
- G. VA Central Office reviews training team's recommendation and has final authority regarding dispensation of the iBOT to the veteran.

Note: In most instances, stair-climbing will be part of the justification for dispensation of the iBOT. If stair climbing is not part of the intended use, the referring station must craft a careful justification as to why the iBOT is likely to be the most sensible solution to complete functional tasks (mobility-related activities of daily living).

V. DISPENSATION CRITERIA

Principles for dispensation of the iBOT:

- A. Potential users must be carefully evaluated to make sure they have the perception and judgment to use the iBOT successfully.
- B. Clear functional goals must be identified for which the iBOT is the most sensible solution.
- C. The iBOT must only be prescribed for use within its tolerances as stated by the manufacturer.
- D. The user must demonstrate understanding and compliance regarding the limits of the iBOT.
- E. The iBOT must fit with the projected environments of use (i.e., iBOT must be able to be transported and function in its intended environments).
- F. The user must understand the risks, benefits, alternatives to the iBOT.
- G. Any problems regarding the iBOT must be reported to the iBOT Training Center, local Wheelchair Clinic Team, and the Prosthetic and Sensory Aids Strategic Healthcare Group, VA Central Office.
- H. The user must be able to perform adequate pressure relief and achieve adequate positioning in the iBOT.
- The patient must undergo training at the one of the designated IBOT
 Training Centers and demonstrate competency in the specific tasks and
 modes of the iBOT.
- J. Approval of issuance of the iBOT to the veteran is received from the Prosthetic and Sensory Aids Service Strategic Healthcare Group, VA Central Office.
- K. In most instances, the VA only provides one power wheelchair. Therefore, a patient receiving an iBOT would forfeit the right to another power

wheelchair (although a manual wheelchair prescription could be considered).

L. These guidelines will be reviewed and updated periodically.

VI. REFERENCES

Clinical Practice Recommendations on Motorized Wheeled Mobility Devices: Scooter, Pushrim-Activated Power-Assist Wheelchairs, Power Wheelchair, and Power Wheelchairs with Enhanced Function - September 2004.

The Canadian Coordinating Office for Healthcare Technology Assessment: Issues in Emerging Health Technologies. Issue 56, May 2004.

Independence iBOT 3000 Mobility System Information Sheet

FDA Release: FDA Approves Stair Climbing Wheelchair - August 12, 2003.

APPROVE/DISAPPROVE:

__Date:__*___*_

Jonathan B. Perlin, MD, PhD, MSHA, FACP Acting Under Secretary for Health

DEPARTMENT OF VETERANS AFFAIRS (VA) VETERANS HEALTH ADMINISTRATION (VHA)

iBOT POWER WHEELCHAIR DESIGNATED VA PATIENT AND CLINICIAN TRAINING FACILITIES

VAMC Washington, DC 50 Irving Street, NW Washington, DC 20422

VAMC Nashville, TN
VA Tennessee Valley Healthcare System
1310 24th Avenue, South
Nashville, TN 37212

VAMC Gainesville, FL
North Florida/South Georgia Veterans
Healthcare System
1601 Southwest Archer Road
Gainesville, FL 32608

VAMC Seattle, WA VA Puget Sound Healthcare System 1660 South Columbian Way Seattle, WA 98108

VAMC Denver, CO VA Eastern Colorado Healthcare System 1055 Clermont Street Denver, CO 80220

VAMC Buffalo, NY 3495 Bailey Avenue Buffalo, NY 14215

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