

Date: **DEC 10 2015**

From: Acting Deputy Under Secretary for Health for Operations and Management (10N)

Subj: Clinical Protocol for Veteran Use of the ReWalk™ Powered Exoskeleton

To: Medical Center Directors

Thru: Network Directors (10N 1-23)

1. This memorandum is to inform Veterans Integrated Service Networks (VISN) and Veterans Affairs Medical Centers of the clinical protocol for Veteran evaluation, training and issuance of the ReWalk™ powered exoskeleton. The ReWalk™ is cleared for marketing by the U.S. Food and Drug Administration (FDA) for use by individuals with spinal cord injury (SCI) who meet identified criteria. The detailed protocol with definitions, Veteran evaluation components, indications and contraindications, and documentation requirements are provided in Appendices A-F.
2. As of December 2015, the ReWalk™ is the only powered exoskeleton cleared by the FDA for issuance to an individual. Powered exoskeletons are a new and emerging technology that require extensive clinical training and expertise. To ensure that Veterans with SCI meet clinical criteria to safely and effectively use the ReWalk, Veterans with SCI interested in being evaluated for use of the device must be referred to one of the 24 Veterans Health Administration SCI Centers.
3. The ReWalk referral process includes (a) Evaluation and (b) Training.
  - a. Evaluation: The Veteran with SCI is referred to one of the 24 SCI Centers. Options for Veteran referral are: 1) Veteran self refers; 2) VA provider contacts the SCI Center; or 3) VA provider contacts the SCI/D System of Care National Program Office for assistance by emailing the **VHA 10NC9 Action** mail group. The SCI team at the SCI Center performs a comprehensive evaluation. Certain components of the evaluation may be completed by telehealth, as determined on a case-by-case basis.
  - b. Training: Once preliminary criteria for ReWalk training are met, including identification of at least one required companion, the Veteran and companion(s) are referred to a VA SCI Center designated as a VA ReWalk Training Center. *A VA ReWalk Training Center is A VA facility that owns or has access to the ReWalk powered exoskeleton and has at least one*

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*clinician who is a certified ReWalk Therapist.* The list of VA SCI/D ReWalk Training Centers is posted on the VA SCI/D intranet page, <http://vawww.sci.va.gov/>. All SCI Centers are encouraged to pursue designation as a ReWalk Training Center. SCI Centers that meet criteria as a ReWalk Training Center must contact the **VHA 10NC9 Action** mailgroup to confirm designation and request addition to the list.

4. When the SCI Center completing the preliminary evaluation is not a ReWalk Training Center and clinician training has not been initiated to support ReWalk Therapist certification, the Veteran is referred to another SCI Center designated as a Training Center. Travel logistics for the patient and the companion are coordinated by the referring SCI Center in collaboration with the training SCI Center. Beneficiary Travel regulations are followed if travel is necessary.
5. The VA ReWalk Therapist and the SCI team at the VA ReWalk Training Center determine if/when the ReWalk is recommended for lease and/or definitive purchase, per established criteria. The Prosthetic and Sensory Aids Service (PSAS) at the training facility is responsible for procurement in collaboration with the VISN Prosthetic Representative and the Network Contracting Office.
6. The Spinal Cord Injury and Disorders (SCI/D) System of Care National Program Office provides oversight for the clinical protocol in collaboration with key stakeholders. Questions about the clinical protocol are directed to the **VHA 10NC9 Action** mail group.
7. This signed memo with the appendices and all related information is posted on the SCI/D System of Care intranet website: <http://vawww.sci.va.gov/>. When the clinical protocol is updated, a new memo highlighting the updates will be disseminated and posted on the SCI/D intranet website.



Janet P. Murphy, MBA

Attachments

cc: SCI/D Center Chiefs  
VISN Prosthetic Representatives  
Chiefs of Staff

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## **Attachment A: Definitions**

1. Powered exoskeleton: As defined by the U.S. Food and Drug Administration (FDA), a powered exoskeleton is a prescription device that is composed of an external, powered, motorized orthosis used for medical purposes that is placed over a person's paralyzed or weakened limbs for the purpose of providing ambulation.
2. ReWalk companion: An adult who has completed required training in accordance with the ReWalk user assessment and training certification program. Specific companion requirements are outlined in "inclusion criteria."
3. Department of Veterans Affairs (VA) ReWalk Training Center: A VA facility that owns or has access to the ReWalk powered exoskeleton and has at least one clinician who is a certified ReWalk Therapist. The list of VA SCI/D ReWalk Training Centers is posted on the SCI/D VA intranet page <http://vaww.sci.va.gov/>.
4. ReWalk Therapist: A clinician who has completed the ReWalk Basic Training certification course.
5. ReWalk Robotics: Formerly Argo Medical Technologies, ReWalk Robotics develops, manufactures and markets the ReWalk powered exoskeleton.
6. ReWalk Rehabilitation System (RS): The ReWalk powered exoskeleton that is adjustable for use with multiple patients and is intended for use in a clinical rehabilitation setting. The controller is carried in a backpack. Customization for individual users is limited. Independent donning and doffing is challenged with multiple adjustable components.
7. ReWalk Personal System (PS): The ReWalk powered exoskeleton that is specifically fit to an individual and is customized for individual use in clinical, home and community settings. The controller is carried in a waist pack which supports center of gravity control. The components and configuration provide optimal skin protection and lower extremity control to advance walking skill progression. Independent donning and doffing is supported by the customized configuration. The ReWalk PS is recommended for definitive clinical training before independent use in home and community settings.
8. SCI team: The interdisciplinary group of SCI experienced clinicians and administrative personnel involved in coordinating care and services for Veterans with SCI. As related to the ReWalk clinical protocol, the SCI team includes at minimum a physician, physical therapist, social worker, and Prosthetic and Sensory Aids Service (PSAS) representative.

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## **Attachment B: Clinical Protocol Outline**

- 1) The Veteran with SCI is referred to the regional SCI Center where specialized care is received. The SCI team at the SCI Center performs a comprehensive evaluation as outlined in attachment C. All inclusion criteria and exclusion criteria represented in attachment D must be met and ruled out respectively to initiate ReWalk training.
- 2) Once preliminary criteria for ReWalk training are met including identification of at least one required companion if definitive issuance will be pursued, a patient treatment plan with measurable short and long term goals is established. Identified goals guide progression, document skill acquisition, and determine objective outcomes.
  - At least one goal must be related to an activity that the Veteran performs while using the ReWalk or as a result of using the ReWalk.
  - Recommended standardized outcome measures include but are not limited to the 10M Walk Test, the Timed Up and Go Test, the Functional Reach Test, the Functional Mobility Assessment, step counting and quality of life measures.
- 3) The Veteran and required companion(s) are referred to a VA SCI Center designated as a VA ReWalk Training Center, which may or may not be the same facility where the preliminary evaluation was performed.
  - When the Veteran and companion(s) are referred to another SCI Center, collaboration between the referring and receiving teams is necessary to confirm evaluation findings, review the treatment plan, coordinate travel, schedule appointments, and coordinate all related patient care and follow up. Assistance is available from the SCI/D System of Care National Program Office through the **VHA National SCI Interfacility Request** mail group.
  - Associated travel for the Veteran and companion(s) will be managed in accordance with VHA policy on travel and lodging for patients, spouses and significant others.
  - Each VA ReWalk Training Center will determine capacity to provide evaluations and training for patients from outside their assigned catchment area based on considerations such as therapy staffing, patient census, and equipment availability.
- 4) Prior to initiating training with the ReWalk, informed consent is obtained from the Veteran as outlined in VHA Handbook 1004.01. In addition to potential risks associated with using the device, the signed informed consent acknowledges required supervision by a trained companion when the Veteran uses the ReWalk. The iMedConsent™ software program is mandated for documenting the informed consent process; a templated example of pertinent information is provided (attachment F).
- 5) A VA ReWalk Therapist provides initial Veteran training with the ReWalk RS either owned by the VA facility or provided by ReWalk Robotics for preliminary trial and training. When ReWalk Robotics or an affiliated entity provides the ReWalk RS for initial Veteran training, the local medical center policy for management of trial, demonstration and/or loaned equipment must be observed.

6) After the Veteran achieves minimum preliminary skills (listed below) and is being treated as an outpatient, trial of the ReWalk PS is coordinated. When the trial device will be leased for an individual Veteran, a PSAS consult is entered. Approval to lease the ReWalk PS is determined locally; national level review is not indicated.

- Minimum preliminary skills demonstrated by the Veteran for trial and/or lease of the ReWalk PS follow. Skill acquisition must be clearly documented in the Computerized Patient Record System (CPRS) in a summary progress note that is referenced in the PSAS consult.
  - a) Transfers into the ReWalk with standby assist.
  - b) Completes sit <-> stand transfers in the ReWalk with standby assist.
  - c) Manages all communicator watch functions independently.
  - d) Completes 50 percent of process to don and doff the ReWalk.
  - e) Walks at least 10 meters in the ReWalk RS with minimum assist.

7) Training continues in the clinical setting. The Veteran and companion(s) are cleared by the clinical team to use the ReWalk PS in home and community settings when all of the following are met:

- Comprehensive basic and advanced skills are achieved and documented. The ReWalk skills inventory lists (attachment E) are signed by the therapist, Veteran and companion(s), and entered in CPRS.
- Comprehensive education and training provided to both the Veteran and required companion(s) are documented in CPRS for each training session. Education regarding the required supervision of a trained companion(s) whenever the Veteran uses the ReWalk must be provided consistently and clearly documented in the medical record.
- A home visit is completed with the Veteran and trained companion(s) to review all skills and confirm a safe environment inside and outside. The evaluation is performed either in-person by a qualified VA clinical provider or by virtual methods (e.g., video to home telehealth visit or review of videos, photos and schematics with measurements submitted by the Veteran).
- The Veteran and companion(s) receive instructions for:
  - a) Device maintenance;
  - b) Requesting and coordinating repairs and/or technology support;
  - c) Determining the need for additional clinical training;
  - d) Contacting the SCI team; and
  - e) The process for reporting adverse events.

8) The SCI team communicates the follow up plan to the Veteran and companion(s). To support safety and outcome measurement, the clinical team communicates with the Veteran daily (Monday through Friday) during the first week and weekly thereafter to confirm compliance with ReWalk use, to assess progress toward identified goals, and to problem solve challenges encountered.

9) The Veteran uses the ReWalk PS in home and community settings under supervision of the trained companion(s) for a minimum of 45 days. The SCI team determines if definitive purchase of the ReWalk PS is potentially indicated after extended trial.

10) The SCI/D System of Care National Program Office reviews all recommendations for definitive purchase of the ReWalk PS. The SCI team submits substantiating information, including CPRS documentation and an itemized quote, by encrypted email to the **VHA 10NC9 Action** mail group. Once approval is received by email, the prescribing clinician submits a consult to the medical center Prosthetic and Sensory Aids Service (PSAS) through CPRS, referencing the approval, substantiating CPRS documentation and the itemized quote.

Definitive purchase is potentially indicated when all of the following are met and clearly documented in CPRS in a summary progress note:

- All skills identified in the ReWalk Basic Skills Inventory and Advanced Skills Inventory are demonstrated by the Veteran and companion(s). Inventory forms are signed and included in CPRS.
- Under the supervision of the required trained companion(s), the Veteran consistently uses the ReWalk in home and community settings for a minimum of 30 minutes, 3 to 5 times per week, for at least 45 days.
- The Veteran's objective goals are achieved or significant progress is evident.
- Goals for continued use are identified.
- All identified challenges are resolved.
- The Veteran receives education that powered exoskeletons are an emerging technology; therefore new devices are likely to be commercially available in the near future. Per VHA Handbook 1173.1, the device will not be replaced for the sole purpose of obtaining a newer model.

11) The Veteran continues to use the ReWalk PS following definitive issuance under supervision of the required companion(s). The SCI team coordinates frequent and consistent follow-up with the Veteran and companion(s) to review standardized outcome measures along with participation, life satisfaction, physical, physiologic, and functional outcomes, daily usage patterns and barriers, neurologic, orthopedic and integumentary status, functional skill acquisition, and device utilization and management in varied environments.

12) The SCI/D System of Care National Program Office monitors and tracks nationwide VHA ReWalk activity including initial Veteran interest in being evaluated for the device, preliminary evaluations complete, training accomplished, devices provided through lease and/or purchase, and adverse events. Veteran outcomes will be recorded, analyzed and summarized to support future VA policy determination for provision of exoskeleton technologies.

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### **Attachment C: Veteran Evaluation**

A preliminary comprehensive interdisciplinary evaluation and assessment, performed by providers at a VA SCI Center, is coordinated and documented in the Veteran's medical record.

Critical components include but are not limited to:

- a. Patient demographics
- b. Past medical history
- c. Current neurologic examination capturing level of injury and impairment
- d. Functional evaluation
  - Wheeled mobility skills
  - Transfers
  - Self-care/activities of daily living
- e. Physical examination including:
  - i. Lower extremity (LE) and upper extremity (UE) range of motion
  - ii. LE and UE strength
  - iii. Muscle tone/spasticity
  - iv. Hand strength and function
- f. Anthropometric measures including:
  - i. Height
  - ii. Weight
  - iii. Leg lengths
    1. Upper Leg Length (in cm): measured from the most prominent point of the greater trochanter to the mid knee joint line.
    2. Lower Leg length (in cm): measured from mid knee joint line to the bottom of foot.
- g. Skin integrity
- h. Bone mineral density at the hip and knee
- i. Autonomic function to include:
  - i. Resting blood pressure (BP)
  - ii. Upright/standing BP
  - iii. Management of autonomic dysreflexia
- j. Cognition

k. Psychosocial assessment

- Includes identification of at least one reliable companion that will participate in required comprehensive training and will provide supervision if/when the Veteran uses the device in home and community settings. Companion criteria are identified in Attachment D.

l. Environmental assessment

- Includes evaluation of designated locations where the ReWalk is likely to be used by the Veteran (e.g., home, work, school, homes of friends and/or family members; includes indoor and outdoor review as needed). The evaluation is performed either in-person by a qualified VA clinical provider or by virtual methods (e.g., CVT to home telehealth visit or review of videos, photos and schematics with measurements submitted by the Veteran).

m. Vision

n. Pregnancy for female patients

o. Identification and documentation of any risks for using the device in home and community settings

p. Referral to the SCI Social Worker to be evaluated for travel considerations for Veterans who must travel to a VA ReWalk Training Center

- i. Includes associated functional, cognitive and psychosocial skills and ability to be away from home for an extended period of time;
- ii. Determination of travel support options for the Veteran and companion including beneficiary travel (BT) eligibility, access to Veterans Transportation Service (VTS), and/or education that Veteran may be responsible for travel costs;
- iii. The social worker at the referring center will collaborate with the social worker at the training site to coordinate resources and to develop a plan for both travel and lodging, when indicated.

The comprehensive interdisciplinary evaluation and assessment documents the extent to which inclusion criteria are met and exclusion criteria are ruled out (Attachment D).



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## **Attachment D: Inclusion and Exclusion Criteria**

### **Inclusion Criteria:**

- a. Patient has a SCI documented by neurologic exam from a VA physician, and the level of injury is confirmed at T4 or below, American Spinal Injury Association (ASIA) Impairment Scale (AIS) A,B,C or D. *The ReWalk is cleared for marketing by FDA for use by individuals with spinal cord injury (SCI) at the seventh thoracic vertebra (T7) to the fifth lumbar vertebra (L5) when accompanied by a specially trained companion and by individuals with SCI at the fourth thoracic vertebra (T4) to the sixth thoracic vertebra (T6) in clinical settings. Prescription of the ReWalk PS for an individual with SCI above T7 or with a diagnosis other than SCI is considered an "off-label" application.*
- b. Patient's functional skills related to wheeled mobility, transfers, and self-care are optimized. *The exoskeleton is not intended to substitute for a wheelchair, therefore optimal wheeled mobility skills are needed for everyday mobility. Transfers and self-care are also essential skills for ReWalk use.*
- c. Patient has functional use of both hands and adequate upper limb strength and coordination to safely and effectively use bilateral forearm crutches for static and dynamic standing.
- d. Patient is 18 years of age or older.
- e. Patient weighs <220 lbs. (<100 kg) and is between 5'2" and 6'2" in height.
- f. At least one companion is identified who meets the following criteria:
  1. The companion is 18 years of age or older;
  2. The companion is able-bodied, with all limbs fully functioning;
  3. The companion is able to bend, stoop, squat, and kneel;
  4. The companion demonstrates understanding of the associated commitment (attending a minimum of three training sessions and walking at home or in the community with the participant whenever the participant uses the device);
  5. The companion demonstrates understanding that the companion and the user are examined as one team for the Advanced Skill set;
  6. The companion is deemed appropriate for training by the SCI team.

### **Exclusion Criteria:**

- a. Diagnosis of neurological injury other than SCI;
- b. Functional skills for wheeled mobility, transfers, and/or self-care are not optimized;
- c. Hand function and upper extremity strength and coordination is not consistent with the use of bilateral forearm crutches for static and dynamic standing;
- d. Unstable neurological status or condition;
- e. Severe concurrent medical disease, illness or condition as determined by treating physician.

- f. Any bone fracture within the past 2 years that is not fully healed;
- g. Any history of a fragility or pathological fracture (e.g., cancer or metabolic etiology);
- h. Extremely low BMD or T-score value at the hip and/or an extremely low BMD value at the knee should be considered relative exclusion criteria for patients who are being considered for exoskeleton use. Establishing absolute BMD and/or T-score threshold values for skeletal regions of interest that would serve to prevent patients from receiving prescription for these devices, although clearly advantageous, is not possible at this time due to lack of evidence-based guidelines.
- i. Untreatable severe spasticity based on Modified Ashworth scale of  $\geq 3$  as judged by the treating physician and/or physical therapist;
- j. Flexion contracture  $\geq 0^\circ$  degrees (neutral) at the hip,  $\geq 10$  degrees at the knee and/or plantarflexion contracture of  $>0$  degrees (neutral);
- k. Untreated or uncontrolled hypertension (guideline is resting systolic BP  $\geq 140$ mmHg; resting diastolic BP  $\geq 90$ mmHg);
- l. Unresolved orthostatic hypotension with sustained supported standing on a tilt table or in a standing frame;
- m. Current pressure ulcer of the trunk, pelvic area or lower extremities;
- n. Psychopathology documentation in the medical record or history that may conflict with treatment objectives;
- o. Pregnancy;
- p. Inability to properly fit the anthropomorphic measurements to the exoskeleton device:
  - a. Patient weighs more than 220 lbs. (100 kg),
  - b. Patient is under 5'2" tall or over 6'2" tall,
  - c. Leg length discrepancy of  $>2$  inches (5cm) and unable to accommodate using orthopedic lifts or shoes;
- q. Designated environment for use of device is deemed inappropriate;
- r. Unable to designate at least one companion to be trained;
- s. Ambulatory for functional distance and velocity without use of powered exoskeleton;
- t. Uncontrolled autonomic dysreflexia;
- u. Unresolved or untreated deep venous thrombosis;
- v. Colostomy that impairs proper fit of the exoskeleton device, or the colostomy cannot be adequately protected while wearing the exoskeleton device;
- w. Upper extremity and/or lower extremity amputations;
- x. Legal blindness;
  - a. Visual acuity of 20/200 or worse in the better eye with corrective lens
- y. Valid concern for Veteran safety surrounding use of the exoskeleton is identified by the clinical team and documented in the Veteran's medical record.

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**Attachment E: ReWalk Basic and Advanced Skills Inventories**

Form No. FRM0621\_09 Rev. 03 Confidential



**ReWalk Basic Skills Inventory**

ReWalk User	ReWalk Companion		ReWalk Therapist(s)	
Skill*	Date	ReWalk Therapist Score	User Score	Companion Score
Transfers		<small>*Score and date each skill as they are completed</small>		
Manual Joint Adjustment				
Donning/Doffing				
Standing Balance				
Sit-Stand and Stand-Sit				
Communicator Use				
10 M Walk Test $\geq 0.15$ m/s				
Turning (Left, Right, 180)				
Walking Through Doorway				
Stopping				
Graceful Collapse				
Bypass Mode				
Skin Check				
General Equipment				
Wall Rest				

I certify that on / / this User/Companion successfully completed all ReWalk Basic Skills:

(signed by ReWalk Therapist)

I certify that I will use the ReWalk in the manner intended and in accordance with the skills learned above:

(signed by ReWalk User)

(signed by ReWalk Companion)

ReWalk User Scoring Guide (Based on ReWalk Functional Movement Scale)			ReWalk Therapist/Companion Scoring Guide	
Pass	$\geq 5$	Task completed w/supervision or independently	2	Therapist/Companion fully understands the function or key aspects of the skill.
Pass w/ Difficulty	4	Minimal Assist required (User provides $\geq 75\%$ )	1	Therapist/Companion understands the function or key aspect of the skill, but requires prompting.
Fail	$< 4$	Task incomplete or unsafe	0	Task incomplete or unsafe

\*This form to be used in conjunction with DOC0621\_01 Rev 04/DOC0621\_06 Rev 01/DOC0621\_08 Rev 01 Basic Clinical Training Course, Section 8: ReWalk Basic Skills



## ReWalk Advanced Skills Inventory

ReWalk User		ReWalk Companion		ReWalk Therapist(s)	
Skill*	Date	ReWalk Therapist Score	User Score	Companion Score	
Adv Walking Skills - Talking		<small>*Score and date each skill as they are completed</small>			
Adv Walking Skills - Noisy Env.					
Reaching - Counter & Shelf					
Doorway Navigation					
Timed Door Navigation					
Timed Walking					
Sitting on/Standing from Bench					
Ramps					
Side Angle Walking					
Multiple surfaces					
Fall Recovery					
10 M Walk Test $\geq 0.4$ m/s					
6 Minute Walk Test $\geq 110$ m					
Curb Cut-outs					

I certify that on \_\_\_\_ / \_\_\_\_ / \_\_\_\_ this User/Companion successfully completed all ReWalk Advanced Skills:

\_\_\_\_\_  
(signed by ReWalk Therapist)

I certify that I will use the ReWalk in the manner intended and in accordance with the skills learned above:

\_\_\_\_\_  
(signed by ReWalk User)

\_\_\_\_\_  
(signed by ReWalk Companion)

ReWalk User Scoring Guide (Based on ReWalk Functional Movement Scale)			ReWalk Therapist/Companion Scoring Guide	
<b>Pass</b>	$\geq 5$	Task completed w/supervision or independently	2	Therapist/Companion fully understands the function or key aspects of the skill.
<b>Pass w/ Difficulty</b>	4	Minimal Assist required (User provides $\geq 75\%$ )	1	Therapist/Companion understands the function or key aspect of the skill, but requires prompting.
<b>Fail</b>	$< 4$	Task incomplete or unsafe	0	Task incomplete or unsafe

\*This form to be used in conjunction with DOC0621\_04 Rev 04 Advanced Clinical Training Course, Section 2: ReWalk Advanced Skills

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**Attachment F: Template for Informed Consent**

*Data cannot be saved on the blank electronic form VA 10-0431a. The iMedConsent™ software program is mandated for documenting the informed consent process, with exceptions identified in VHA Handbook 1004.01.*

*A template for electronic form VA 10-0431a that includes suggested language for informed consent related to ReWalk use is posted on the VA SCI/D intranet page, <http://vaww.sci.va.gov>*