

Date: JUN - 7 2018

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

Subj: Revised Clinical Protocol for Issuance of Powered Exoskeleton Devices to Veterans with Spinal Cord Injury

To: Medical Center Directors

Thru: Network Directors (10N1-23)

1. This memorandum is to inform Veterans Integrated Service Networks (VISN) and Veterans Affairs (VA) medical centers of the revised clinical protocol for Veteran evaluation, training, and issuance of powered exoskeletons for personal use that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) for use by individuals with a spinal cord injury (SCI) who meet defined criteria. This memorandum rescinds the Acting Deputy Under Secretary for Health for Operations memorandum entitled, Clinical Protocol for Veteran use of the ReWalk™ Powered Exoskeleton, dated December 10, 2015. The detailed revised protocol with definitions, clinical protocol outline, and Veteran evaluation components are provided in Attachments A-C.
2. Powered exoskeletons are new and emerging technologies that require extensive clinical training and expertise. To ensure that Veterans with SCI meet clinical criteria to safely and effectively use powered exoskeletons, Veterans with SCI interested in being evaluated for use of the device and potential support by VA must be referred to one of the VA Spinal Cord Injuries and Disorders (SCI/D) Centers.
3. The powered exoskeleton process includes (a) evaluation and (b) training.
 - a. Evaluation: The Veteran with SCI is referred to one of the VA SCI/D Centers or to the VA SCI/D System of Care National Program Office. The referral may originate from stakeholders including the Veteran with SCI or a VA or non-VA provider, but the Veteran must agree to the referral. The SCI/D team at the VA SCI/D Center performs a comprehensive evaluation. Certain components of the evaluation may be completed by telehealth, as determined on a case-by-case basis. See Attachment C for specific evaluation requirements.
 - b. Training: Once preliminary criteria for powered exoskeleton training are met, including identification of at least one required companion, the Veteran is referred to a VA SCI/D Center that is designated as a VA Exoskeleton Training Center. A VA Exoskeleton Training Center owns or has access to one or more model(s) of powered exoskeleton and has at least one therapist who is trained and certified for that particular model(s).


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The list of VA SCI/D Exoskeleton Training Centers is posted on the VA SCI/D System of Care Intranet page, <http://vawww.sci.va.gov/>.

4. In the case of a Veteran who primarily receives services at a VA facility that is not a VA SCI/D Center, he/she will be referred to the Veteran's designated VA SCI/D Center for an evaluation. The VA SCI/D Center conducting the evaluation is responsible, in collaboration with the home VA facility, for coordination of the patient's travel logistics and is also responsible for applicable beneficiary travel associated expenses.
5. When the VA SCI/D Center completing the preliminary evaluation is not a VA Exoskeleton Training Center and does not have at least one therapist who is certified to provide training on the exoskeleton device for which the Veteran has been evaluated, the Veteran is referred to another VA SCI/D Center designated as a VA Exoskeleton Training Center. The VA Exoskeleton Training Center is responsible, in coordination with the referring VA SCI/D Center and/or home VA facility as appropriate, for coordination of the patient's and companion's travel logistics, and is also responsible for applicable beneficiary travel associated expenses.
6. If a Veteran with SCI/D is unable or unwilling to travel to a VA Exoskeleton Training Center for training, case-by-case consideration will be given to enable the Veteran and companion to receive training at a VA facility that does not have an exoskeleton training program or at a non-VA facility. In these cases, the designated VA SCI/D Center for the Veteran with SCI/D must be involved in the initial evaluation, approval of the training site, community care consult initiation and management, ongoing monitoring of training, and follow-up once the Veteran completes training. SCI/D care and exoskeleton training at the training site must be evaluated and determined to be at least equivalent to that received in a VA Exoskeleton Training Center. The non-SCI/D Center facility that provides training to the Veteran with SCI/D must follow this clinical protocol and provide documentation to the VA SCI/D Center that was involved in the evaluation and approval of the non-SCI/D Center training site. The Veteran's designated VA SCI/D Center is responsible, in coordination with the Veteran's home VA facility as appropriate, for coordination of the patient's and companion's travel logistics and is also responsible for applicable beneficiary travel associated expenses.

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7. In collaboration with the Veteran, the SCI/D team, including the Certified Exoskeleton Therapist, at the VA Exoskeleton Training Center will determine which powered exoskeleton is most appropriate for a particular patient. The Prosthetic and Sensory Aids Service at the training facility is responsible for procurement, in collaboration with the VISN Prosthetic Representative and the Network Contracting Office.
8. VA Beneficiary Travel regulations and policies are to be followed for all travel associated with exoskeleton evaluation and training. As appropriate, other components of the Veterans Transportation Program may be utilized.
9. The SCI/D System of Care National Program Office (10NC9) provides oversight for the clinical protocol, in collaboration with key stakeholders. Questions about the clinical protocol are to be directed to the VHA 10NC9 Action mail group.
10. This signed memorandum with appendices and all related information is posted on the VA SCI/D System of Care Intranet website: <http://vaww.sci.va.gov>. When the clinical protocol is updated, a new memorandum highlighting the updates will be disseminated and posted on the VA SCI/D System of Care Intranet website.


for Steve Young

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

Subject: *Powered Exoskeleton Clinical Protocol*

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. Companion: An adult who has completed required training in accordance with the prescribed powered exoskeleton training certification program for Veterans with SCI who will be issued an exoskeleton for personal use. Specific companion requirements are stated by the manufacturer and FDA.
3. Department of Veterans Affairs (VA) Exoskeleton Training Center: A VA facility that owns or has access to one or more model(s) of powered exoskeleton and has at least one therapist who is trained and certified for that particular model(s). The list of VA Exoskeleton Training Centers is posted on the VA SCI/D System of Care Intranet page, <http://vawww.sci.va.gov>.
4. Certified Exoskeleton Therapist: A therapist who has completed the basic and/or advance training certification course for a particular model of exoskeleton.
5. Spinal Cord Injury and Disorders (SCI/D) Team: The interdisciplinary group of SCI/D experienced clinicians and administrative personnel involved in coordinating care and services for Veterans at SCI/D Centers. For exoskeleton education, training, and procurement, a team will typically involve a physician, physical therapist, social worker, and Prosthetic and Sensory Aids Service representative.

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Attachment B: Clinical Protocol Outline

1) The Veteran with a spinal cord injury (SCI) is referred to a Department of Veterans Affairs (VA) spinal cord injuries and disorders (SCI/D) Center. The SCI/D team at the VA SCI/D Center performs a comprehensive evaluation as outlined in Attachment C. Inclusion and exclusion criteria, as specified by the manufacturer and the U.S. Food and Drug Administration, must be satisfied to initiate exoskeleton training.

2) Once preliminary criteria for powered exoskeleton training are met, a VA SCI/D Center designated as a VA Exoskeleton Training Center is identified, 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 VA SCI/D Center, collaboration between the referring and receiving teams is necessary to confirm evaluation findings (including bone density evaluation), review the treatment plan, coordinate travel, schedule appointments, and coordinate all related patient care and follow up. Additional administrative guidance is available from the VA SCI/D System of Care National Program Office through the **VHA 10NC9 Action** mail group.
- Associated travel and lodging for the Veteran and companion(s) will be managed in accordance with Veterans Health Administration (VHA) policy on travel and lodging for Veterans, spouses, and significant others, including VHA Handbook 1601B.05, Beneficiary Travel, dated July 21, 2010; VHA Directive 1107, VA Fisher Houses and Other Temporary Lodging, dated March 10, 2017; and the Deputy Under Secretary for Health for Operations and Management memorandum, Eligibility for Beneficiary Travel for Special Disabilities Care, dated March 2, 2017; or subsequent policies.
- Each VA Exoskeleton Training Center will determine capacity to provide evaluations and training for Veterans from outside their assigned catchment area based on considerations such as therapy staffing, patient census, and equipment availability.
- If a Veteran with SCI/D is unable or unwilling to travel to a VA Exoskeleton Training Center for training, case-by-case consideration will be given to enable the Veteran and companion to receive training at a VA facility that does not have an exoskeleton training program or at a non-VA facility. In these cases, the designated VA SCI/D Center for the Veteran with SCI/D must be involved in the

initial evaluation, approval of the training site, community care consult initiation and management, ongoing monitoring of training, and follow-up once the Veteran completes training. SCI/D care and exoskeleton training at the training site must be evaluated and determined to be at least equivalent to that received in a VA Exoskeleton Training Center.

3) Prior to initiating training with any powered exoskeleton, informed consent is obtained from the Veteran as outlined in VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009, or subsequent policy. 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 powered exoskeleton. The iMedConsent™ software program is mandated for documenting the informed consent process.

4) A Certified Exoskeleton Therapist provides initial Veteran training with the powered exoskeleton either owned by the VA facility or provided by the device manufacturer for preliminary trial and training. When the powered exoskeleton manufacturer or an affiliated entity provides the powered exoskeleton for initial Veteran training, the local medical center policy for management of trial, demonstration and/or loaned equipment must be observed.

5) After the Veteran achieves minimum preliminary skills (listed below) and is being treated as an outpatient, trial of the powered exoskeleton is coordinated. When the trial device is recommended for lease for an individual Veteran, a Prosthetic and Sensory Aids Service (PSAS) consult is entered. Approval to lease the powered exoskeleton is determined locally, national level review is not indicated.

- Minimum preliminary skills demonstrated by the Veteran and companion for trial and/or lease of the powered exoskeleton 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 powered exoskeleton with standby assist.
 - b) Completes sit-to-stand and stand-to-sit transfers in the powered exoskeleton with stand-by assist.
 - c) Manages all device control functions independently.
 - d) Completes 50 percent of process to don and doff the powered exoskeleton.
 - e) Walks at least 10 meters in the exoskeleton with minimal assist.

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

- Comprehensive skills are achieved and documented. The appropriate

manufacturer skills inventory lists are signed by the Certified Exoskeleton Therapist, Veteran and companion(s), and entered in CPRS.

- Comprehensive education and training provided to both the Veteran and required companion(s) are successfully completed and documented in CPRS for each training session. Education regarding the required supervision of a trained companion(s) whenever the Veteran uses the powered exoskeleton must be provided consistently and clearly documented in CPRS.
- A home visit is completed with the Veteran and trained companion(s) to review all skills and confirm a safe environment inside and outdoors. The evaluation is performed either in-person by a qualified clinical provider or by virtual methods (e.g., video to home telehealth visit or review of videos, photographs, 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.

The SCI/D team communicates the follow-up plan to the Veteran and companion(s). To support safety and outcome measurement during the device leasing period, the clinical team communicates with the Veteran three times a week during the first week and once per week thereafter during the leasing trial period. Communication is needed to confirm adherence with the powered exoskeleton use, assess for safety, assess progress toward identified goals, and to problem solve challenges encountered. Each facility that provides training is highly encouraged to collect objective clinical outcome measurement data. At this time, there are no uniform, universally accepted outcome measures.

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

- Under the supervision of the required training companion(s), the Veteran consistently uses the powered exoskeleton in home and community settings for a minimum of 30 minutes per session, three or more times per week, for at least 45 days.
- All skills identified in the powered exoskeleton manufacturer's comprehensive skills inventory are demonstrated by the Veteran and companion(s). Inventory forms are signed and included in CPRS.

- The Veteran's objective goals are achieved or significant progress is demonstrated.
- Goals for continued use are identified.
- Identified challenges are resolved.
- There is an in-clinic reassessment of the Veteran's home unit and companion(s) to confirm safety and adherence with all required skills. This reassessment must take place at the same facility that provided exoskeleton training or a facility that will provide equivalent SCI/D care and exoskeleton reassessment.
- 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, Eligibility, dated November 2, 2000, or subsequent policy, the device will not be replaced for the sole purpose of obtaining a newer model.

8) The Veteran continues to use the powered exoskeleton following definitive issuance under supervision of the required companion(s). The SCI/D team coordinates frequent and consistent follow-up with the Veteran and companion(s)

Subject: *Powered Exoskeleton Clinical Protocol*

Attachment C: Veteran Evaluation

A preliminary comprehensive interdisciplinary evaluation and assessment, performed by providers at a Department of Veterans Affairs (VA) Spinal Cord Injury and Disorders (SCI/D) Center, is coordinated and documented in the Veteran's medical record in the Computerized Patient Record System.

A comprehensive interdisciplinary evaluation and assessment documents the extent to which inclusion criteria are met and exclusion criteria are satisfied. The inclusion and exclusion criteria must follow indications for use and limitations as specified by the manufacturer and U.S. Food and Drug Administration clearance.

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. Muscletone/spasticity
 - iv. Hand strength and function
- f. Anthropometric measures including:
 - i. Height
 - ii. Weight
 - iii. Leg lengths
- g. Skin integrity
- h. Bone mineral density at the hip (required) and knee (if available): bone density evaluation to be completed at referring facility.
- i. Autonomic function to include:
 - i. Resting blood pressure (**BP**)
 - ii. Upright/standing **BP**
 - iii. Management of autonomic reflexia

j. Cognition

k. Psychosocial assessment

- Includes identification of at least one reliable companion who will participate in required comprehensive training and will provide supervision if/when the Veteran uses the device in home and community settings.

l. Environmental assessment

- Includes evaluation of designated locations where the powered exoskeleton 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., Clinical Video Telehealth to home telehealth visit or review of videos, photographs 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/D Social Worker to be evaluated for travel considerations for Veterans that must travel to a VA Exoskeleton Training Center including:

- i. 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 eligibility, access to Veterans Transportation Service, 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.