Powered Exoskeleton Issuance Clinical Guidelines

Purpose: This document provides guidance on the appropriate prescription of powered exoskeleton devices for Veterans, with guidance for Clinical and Prosthetic and Sensory Aids Service (PSAS) personnel. This document outlines the process for evaluation, training, rental period and procurement of powered exoskeleton technology. *Attachment A* provides specific guidelines for the components of a comprehensive evaluation, while *Attachment B* provides additional considerations for fracture risk.

This document rescinds the Deputy Under Secretary for Health for Operations and Management memorandum entitled, Revised Clinical Protocol for Issuance of Powered Exoskeleton Devices to Veterans with Spinal Cord Injury, dated June 7, 2018.

Background: Powered exoskeleton devices are FDA cleared wearable robotic devices that are battery powered, utilizing motors and computers to allow for gait.

Authority: 38 CFR §17.3200 – 17.3250

eCFR :: 38 CFR Part 17 - Prosthetic and Rehabilitative Items and Services

Responsible Program Office: Spinal Cord Injuries and Disorders (11SCI/D)

Clinical Guidance:

1. Inclusion and exclusion criteria, as specified by the manufacturer and the U.S. Food and Drug Administration, must be satisfied to initiate exoskeleton training. At the time of the publication of this SOP, only individuals with spinal cord injury (SCI) are cleared for community use of powered exoskeleton devices. Additional diagnoses may be appropriate for clinical training.

2. **Evaluation:** The Veteran with a SCI is referred to a Department of Veterans Affairs (VA) Spinal Cord Injuries and Disorders (SCI/D) Center for a comprehensive evaluation (outlined in Attachment A)

3. **Training:** Once criteria for powered exoskeleton training are met and the appropriate device is determined, a training facility is identified. Preference is for exoskeleton training to occur at a VA SCI/D Center. However, training can also occur at a VA SCI/D spoke facility, or community facility where staff have appropriate certification and experience in training on the device prescribed by the SCI/D center.

   If training occurs outside of a VA SCI/D Center, the designated VA SCI/D Center for the Veteran 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.

4. **Beneficiary travel:** Associated travel and lodging for the Veteran and companion(s) will be managed in accordance with beneficiary travel. Information regarding travel and lodging located Veterans Transportation Program (VTP) - Health Benefits (va.gov)

5. **Preliminary Trial:** A "preliminary trial" is a part of the evaluation process and includes the first 1-5 sessions of exoskeleton use in the clinic. It is necessary to determine if the Veteran is capable of basic skill acquisition to continue participation in clinical training. A Certified Exoskeleton Therapist participates in the preliminary trial with the powered exoskeleton either owned by the VA facility or provided by the device manufacturer. 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.

   It is recommended that the Veteran be provided with education regarding all appropriate device options to allow for informed participation by the Veteran in the exoskeleton device selection process.

   Explicit goal(s) must be defined for the use of an exoskeleton device.

   Minimum Preliminary skills as observed by exoskeleton therapist:

   a. Adequate safety with transfers into the device.
   b. Completes sit-to-stand and stand-to-sit transfers in the powered exoskeleton with minimal assist.
   c. Demonstrates ability to learn control functions.
   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 without adverse events.

   Once the Veteran achieves minimum preliminary skills, lease of the powered exoskeleton for continued clinical training may be coordinated. (This step is not necessary for facilities that own a device for training purposes.) When the trial device is recommended for lease for an individual Veteran, a Prosthetic and Sensory Aids Service (PSAS) consult/order is entered. Therapists should reference the documentation of preliminary clinical trial (note title/date) within the PSAS consult/order (if rental needed for ongoing clinical training) Approval to lease the powered exoskeleton is determined locally, national level review is not indicated.

6. **Clinical Training:**
   Issuance of a powered exoskeleton should only be considered when Veteran has plateaued in their progress towards ambulatory goals with conventional gait training equipment (e.g. bracing, assistive devices) at an ambulatory level below that which can be achieved with the exoskeleton device.

Veteran and companion(s) must complete the following during clinical training to proceed to the Home Trial Period:

- Comprehensive education and training provided to both the Veteran and required companion(s) are successfully completed and documented for each training session.
- The manufacturer skills inventory lists are signed by the Certified Exoskeleton Therapist, Veteran and companion(s), and entered in the EHR.
- A home or community assessment of location(s) of intended use is completed by the certified exoskeleton therapist with the Veteran and trained companion(s) to review all skills and confirm a safe environment . The evaluation is performed either in-person or by virtual methods.
- 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).

7. **Home Trial Period:** Definitive purchase is potentially initiated when all of the following are met and clearly documented in the EHR in a summary progress note:
    - Veteran consistently uses the powered exoskeleton in home and community settings during a 45 day home use rental period. Clinician and Veteran should define expected use prior to home trial. Recommended minimum of 3x 30 minutes or total of 90 minutes/week unless unique patient circumstances require modification of recommended use, based on exoskeleton clinician's clinical judgement.
    - All skills identified in the powered exoskeleton manufacturer's comprehensive skills inventory are demonstrated by the Veteran and companion(s). Inventory forms are verified by the clinician, filed with the manufacturer, and included in the EHR.
    - Veteran specific goals must be established for both the period of the lease and for continued use of the device prior to procurement. Progress towards goals must be demonstrated during the trial period.
    - The SCI/D team communicates with the Veteran once per week during the leasing trial period. Communication is needed for: usage, safety, progress toward goals and problem solving. Each facility that provides training is highly encouraged to collect objective clinical outcome measurement data.
    - There is an in-clinic or virtual reassessment of the Veteran's home unit with companion(s) to confirm safety and adherence with all required skills following the home trial period

8. **Issuance:** 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), annually at a minimum.
9. **Additional administrative guidance** is available from the VA SCI/D National Program Office. Please email VHA11SCIDACTION@va.gov. Additional clinical information and peer support is available at Exoskeleton-Assisted Ambulation Programs | General | Microsoft Teams

Prosthetics Guidance:

2641 is **not** required for the procurement of this device.

The following should be included in treatment documentation/consult/order to Prosthetics

- Medical Diagnosis, functional loss, and comorbidities
- Clinical justification of the device as a direct and active component of the Veteran's medical and/or rehabilitation treatment program
- Inclusion of treatment specific goals that can only be achieved with the use of an exoskeleton
- Documentation of successful clinical training for home trial period.
- Documentation of successful home trial period of device for purchase of device.
- Training and education on equipment or device to be provided.

Clinically prescribed device should include make/model and proper ordering information on the consult/order. Clinicians should work with prosthetics to obtain an accurate quote for this device for the home trial phase.

Procurement is a 2-Phase process that involves completion of a successful home trial rental period prior to final purchase:

1. The clinician will place a consult or order to Prosthetics for a 60 Day Device Rental. This will be procured by PSAS to ensure successful in home trial. Upon completion of the 45 day in home trial, the prescribing clinician will review findings from the home trial and determine if the Veteran has met the criterion for purchase (see above). Supporting documentation should be include in the Veteran's EHR.
2. If the Veteran has met all criterion for successful home trial (see above), the prescribing clinician will place a consult/order to Prosthetics for purchase. Final purchase will be procured by Prosthetics.

HCPC: K1007

This document was updated on 09/30/2024 by the Spinal Cord Injuries and Disorders National Program Office and Physical Medicine and Rehabilitation National Program Office in collaboration with the National Prosthetic and Sensory Aids Service. This guidance will be reviewed on a bi-annual basis.

Attachment A: SCI Veteran Exoskeleton 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 electronic medical record.

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:
    - Lower extremity (LE) and upper extremity (UE) range of motion
    - LE and UE strength
    - Muscle tone/spasticity
    - Hand strength and function
f. Anthropometric measures including:
    - Height
    - Weight
    - Leg lengths
    - Hip width
g. Skin integrity
h. Fracture Risk (see attachment B for additional guidance)
i. Autonomic function to include:
    - Resting blood pressure (BP)
    - Upright/standing BP
    - 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 primary locations where the powered exoskeleton is likely to be used and stored 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 or by virtual methods (e.g., telehealth or review of videos, photographs and schematics with measurements submitted by the Veteran) by a qualified VA clinical provider.

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:
    - Functional, cognitive and psychosocial skills and ability to be away from home for an extended period of time.
    - 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.
    - 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.

Attachment B: Fracture Risk Assessment for Exoskeleton Use in Veterans with SCI

- There is currently no established threshold for bone mineral density (BMD) value for which weight bearing activities are absolutely contraindicated and full assessment of risk should be considered.
- Veteran should be advised of their fracture risk prior to utilizing exoskeleton technology.
- Consideration for implementation of a progression algorithm may be appropriate for Veterans with osteoporotic or osteopenic profiles.

ABSOLUTE CONTRAINDICATIONS:

- History of previous **fragility fracture** in the lower extremity is an **absolute** contraindication and no further imaging is indicated. *Confirmed evidence of a healed traumatic fractures is not an exclusion criteria. (see table below for definitions)*
- **Required imaging**: Bilateral foot x-rays to rule out pre-existing fragility fractures, **presence of foot fracture is an absolute contraindication**. Evidence of osteoporosis without fracture should be considered within the broader context of the individuals fracture risk profile.

RELATIVE CONTRAINDICATIONS:

Hip DXA T-Score <-3.5 and/or Knee DXA <.6g/cm^2

- **Highly recommended**: proximal femur DXA - While no definitive thresholds have been established, previous studies have used proximal femur T-score of <-3.5.
- **Recommended (if available)**: distal femur/proximal tibia DXA – While no definitive thresholds have been established, previous studies have used <0.6g/cm2 as recommended cut-off values. (GE iDXA ortho knee software application)

CONSIDERATIONS:

- Decreased bone density observed on foot x-ray
- Prolonged absence of weight bearing activity
- Known factors related to elevated fracture risk:
  - Alcohol intake >5 servings per day
  - Current smoker
  - Paraplegia
  - Duration of SCI > 10 years
  - Motor complete injury (AIS A or B)
  - Osteoporosis in first degree relative
  - Routine use of benzodiazepines
  - Routine use of opioid analgesia (> 28mg morphine for a 3 month period)

Fragility fracture is defined by minimal trauma or low impact fracture. Examples include:

- Fracture that occurred without the person having knowledge of the occurrence or cause.
- Fracture that resulted from a fall from a wheelchair, bed, toilet, etc.
- Fracture that occurred while performing stretching
- Fracture that resulted from, or during, a transfer.
- Fracture from bumping or banging the lower extremity.
- Fracture from dropping the foot to the ground or wheelchair footplate
- Fracture from a light object falling on any lower extremity body part.
- Fracture from carrying something or someone in their lap.

Traumatic or high impact fracture are any fractures that occur from a forceful event such as motor vehicle accidents, fall from height greater than adult height standing and/or from a heavy object falling on the lower extremity.

References/Resources:

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Spungen, A. M., Bauman, W. A., Biswas, K., Jones, K. M., Snodgrass, A. J., Goetz, L. L., ... & Huang, G. D. (2020). The design of a randomized control trial of exoskeletal-assisted walking in the home and community on quality of life in persons with chronic spinal cord injury. *Contemporary clinical trials*, *96*, 106102. https://www.sciencedirect.com/science/article/pii/S1551714420301804

Craven, B. C., Giangregorio, L. M., Côté, I., Blencowe, L., Miyatani, M., & Alavinia, M. (2023). Using Risk Scores to Estimate Lower Extremity Fragility Fracture Risk among Individuals with Chronic Spinal Cord Injury: A Preliminary Model. *Topics in Spinal Cord Injury Rehabilitation*, *29*(Supplement), 112-113.

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Bass, A., Aubertin-Leheudre, M., Morin, S.N. *et al.* Preliminary training volume and progression algorithm to tackle fragility fracture risk during exoskeleton-assisted overground walking in individuals with a chronic spinal cord injury. *Spinal Cord Ser Cases* **8**, 29 (2022). https://doi.org/10.1038/s41394-022-00498-7

Additional Resources:

www.scifragments.ca