



Powered Exoskeleton for Ambulation and Rehabilitation

Effective: November 1, 2024

Next Review: August 2025

Last Review: September 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Powered exoskeletons for ambulation are designed to enable people who do not have volitional movement of their lower extremities to be able to fully bear weight while standing, to walk, and to navigate stairs. Powered exoskeletons for rehabilitation are designed to provide therapist-assisted and remote robot-assisted repetitive task physical therapy. The devices have the potential to restore mobility and, thus, might improve functional status, quality of life, and health status for such patients.

MEDICAL POLICY CRITERIA

Use of a powered exoskeleton for ambulation and/or rehabilitation is considered **investigational**.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. [Definitive Lower Limb Prostheses](#), Durable Medical Equipment, Policy No. 18
2. [Myoelectric Prosthetic and Orthotic Components for the Upper Limb](#), Durable Medical Equipment, Policy No. 80

3. [Powered and Microprocessor-Controlled Knee and Ankle-Foot Prostheses, and Microprocessor-Controlled Knee-Ankle-Foot Orthoses](#), Durable Medical Equipment, Policy No. 81
4. [Upper Extremity Rehabilitation System with Brain-Computer Interface](#), Durable Medical Equipment, Policy No. 94

BACKGROUND

An exoskeleton is an external structure with joints and links that might be regarded as wearable robots designed around the shape and function of the human body. A powered exoskeleton consists of an exoskeleton-like framework worn by a person that includes a power source supplying energy for limb movement.

One type of powered lower-limb exoskeleton, which includes the ReWalk™ Personal 6.0 (ReWalk Robotics) and the Indego® (Parker Hannifin), provides user-initiated mobility based on postural information. Standing, walking, sitting, and stair up/down modes are determined by a mode selector on a wristband. ReWalk™ includes an array of sensors and proprietary algorithms that analyze body movements (e.g., tilt of the torso) and manipulate the motorized leg braces. The tilt sensor is used to signal the onboard computer when to take the next step. Patients using the powered exoskeleton must be able to use their hands and shoulders with forearm crutches or a walker to maintain balance. Instructions for ambulating with ReWalk™^[1] are to place the crutches ahead of the body, and then bend the elbows slightly, shifting weight toward the front leg, leaning toward the front leg side. The rear leg will lift slightly off of the ground and then begin to move forward. Using the crutches to straighten up will enable the rear leg to continue moving forward. The process is repeated with the other leg.

To move from a seated to standing position or vice versa, the desired movement is selected by the mode selector on the wrist. There is a five-second delay to allow the individual to shift weight (forward for sit-to-stand and slightly backward for stand-to-sit) and to place their crutches in the correct position. If the user is not in an appropriate position, a safety mechanism will be triggered. Walking can only be enabled while standing, and the weight shift must be sufficient to move the tilt sensor and offload the back leg to allow it to swing forward. Continuous ambulation is accomplished by uninterrupted shifting onto the contralateral leg. The device can be switched to standing either via the mode selector or by not shifting weight laterally for two seconds, which triggers the safety mechanism to stop walking. Some patients have become proficient with ReWalk by the third week of training.^[2]

The Motus Hand and Motus Foot are sleeve-like robotic exoskeleton devices designed to assist stroke survivors with therapeutic exercises. Equipped with an active-assist air muscle and a suite of sensors and accelerometers, they provide assistance and resistance while individuals perform the needed therapeutic exercises. A touchscreen console provides goal-directed biofeedback through interactive games. These devices are intended for use at home or in the clinic and guide patients through therapeutic activities, providing intuitive robotic assistance to augment weakness and help patients engage in high-dose repetitive task practice. They generate personalized statistics and are intended for non-invasive, external use only. The devices use artificial intelligence technology to monitor user activity and progress in order to adjust the difficulty of the interactive games.

REGULATORY STATUS

In 2014, ReWalk™ (ReWalk Robotics, previously Argo Medical Technologies) was granted a de novo 510(k) classification (K131798) by the U.S. Food and Drug Administration (FDA)

(Class II; FDA product code: PHL). The new classification applies to this device and substantially equivalent devices of this generic type. ReWalk™ is the first external, powered, motorized orthosis (powered exoskeleton) used for medical purposes that is placed over a person's paralyzed or weakened limbs for the purpose of providing ambulation. De novo classification allows novel products with moderate- or low-risk profiles and without predicates that would ordinarily require premarket approval as a Class III device to be down-classified in an expedited manner and brought to market with a special control as a Class II device.

The ReWalk™ is intended to enable individuals with spinal cord injury at levels T7 to L5 to perform ambulatory functions with supervision of a specially trained companion in accordance with the user assessment and training certification program. The device is also intended to enable individuals with spinal cord injury at levels T4 to T6 to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. The ReWalk™ is not intended for sports or stair climbing.

Candidates for the device should have the following characteristics:

- Hands and shoulders can support crutches or a walker
- Healthy bone density
- Skeleton does not suffer from any fractures
- Able to stand using a device such as a standing frame
- In general good health
- Height is between 160 cm and 190 cm (5'3"-6'2")
- Weight does not exceed 100 kg (220 lb).

In 2019, the ReWalk ReStore™, a lightweight, wearable, exo-suit, was approved for rehabilitation of individuals with lower limb disabilities due to stroke.

In 2016, Indego® (Parker Hannifin) was cleared for marketing by the FDA through the 510(k) process (K152416). The FDA determined that this device was substantially equivalent to existing devices, citing ReWalk™ as a predicate device. Indego® is "intended to enable individuals with spinal cord injury at levels T7 to L5 to perform ambulatory functions with supervision of a specially trained companion". Indego® has also received marketing clearance for use in rehabilitation institutions.

In 2016, Ekso™ and Ekso GT™ (Ekso Bionics® Inc) were cleared for marketing by the FDA through the 510(k) process (K143690). The ReWalk™ was the predicate device. Ekso™ is intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for the following populations with upper extremity motor function of at least 4/5 in both arms: individuals with hemiplegia due to stroke; individuals with spinal cord injuries at levels T4 to L5; individuals with spinal cord injuries at levels of C7 to T3.

In 2022, EksoNR™ (Ekso Bionics Inc) was cleared for marketing by the FDA through the 510(k) process (K220988). EksoNR is intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for the following populations: individuals with multiple sclerosis (upper extremity motor function of at least 4/5 in at least one arm); individuals with acquired brain injury, including traumatic brain injury and stroke (upper extremity motor function of at least 4/5 in at least one arm); individuals with spinal cord injuries at levels T4 to L5 (upper extremity motor function of at least 4/5 in both

arms), and individuals with spinal cord injuries at levels of C7 to T3 (ASIA D with upper extremity motor function of at least 4/5 in both arms).

In 2017, Hybrid Assistive Limb (HAL™) for Medical Use (Lower Limb Type) (CYBERDYNE Inc.) was cleared for marketing by the FDA through the 510(k) process (K171909). The ReWalk™ was the predicate device. The HAL is intended to be used inside medical facilities while under trained medical supervision for individuals with spinal cord injury at levels C4 to L5 (ASIA C, ASIA D) and T11 to L5 (ASIA A with Zones of Partial Preservation, ASIA B).

In 2020, Keeogo™ (B-Temia) exoskeleton was cleared for marketing by the FDA through the 510(k) process (K201539). The Honda Walking Assist Device was the predicate device. Keeogo™ is intended for use in stroke patients in rehabilitation settings.

In 2021, ExoAtlet-II® (ExoAtlet Asia Co. Ltd.) was cleared for marketing by the FDA through the 510(k) process (K201473). The Ekso/Ekso GT was the predicate device. ExoAtlet-II is intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for the following populations with upper extremity motor function of at least 4/5 in both arms: individuals with spinal cord injuries at levels T4 to L5, and individuals with spinal cord injuries at levels of C7 to T3 (ASIA D).

In 2022, GEMS-H® (Samsung Electronics Co. Ltd.) was cleared for marketing by the FDA through the 510(k) process (K213452). The Honda Walking Assist Device was the predicate device. GEMS-H is intended to help assist ambulatory function in rehabilitation institutions under the supervision of a trained healthcare professional for individuals with stroke who have gait deficits and exhibit gait speeds of at least 0.4 m/s and are able to walk at least 10 meters with assistance from a maximum of one person.

In 2022, Atalante® (Wandercraft SAS) was cleared for marketing by the FDA through the 510(k) process (K221859). The Indego was the predicate device. Atalante is intended to enable adults with hemiplegia due to cerebrovascular accident, who are able to tolerate a stand-up position, to perform ambulatory functions and mobility exercises, hands-free, in rehabilitation institutions under the supervision of a trained operator. The Atalante X® was cleared for marketing by the FDA through the 510(k) process (K232077) and is intended to perform ambulatory functions and mobility exercises, hands-free, in rehabilitation institutions for individuals with hemiplegia due to cerebrovascular accident and individuals with spinal cord injuries at levels T5 to L5.

The Motus Hand and Foot are Class I FDA-approved devices. The devices are indicated for use for stroke rehabilitation with an in-person physical therapist and for remote at-home use. The devices are designed to increase the dose of repetitive task practice in physical therapy through at-home use.

FDA product code: PHL.

EVIDENCE SUMMARY

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function – including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or

worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. Randomized controlled trials (RCTs) are preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Pre-post study designs (patient as their own control) are most likely to provide evidence on the effects of a powered exoskeleton on health outcomes. Outcomes of interest are the safety of the device, the effect of the exoskeleton on the ability to ambulate, and the downstream effect of ambulation on other health outcomes (e.g., bowel and bladder function, spasticity, cardiovascular health). Of importance in this severely disabled population is the impact of this technology on activities of daily living, which can promote independence and improved quality of life.

Issues that need to be assessed include the device's performance over the longer-term when walking compared with wheelchair mobility, the user's usual locomotion outside of the laboratory setting, and the use of different exoskeletons or the training context.^[3] Adverse events (e.g., falling, tripping) can impact both safety and psychological security and also need to be assessed.

POWERED EXOSKELETON FOR AMBULATION

Clinical Context and Therapy Purpose

An exoskeleton is an external structure with joints and links that might be regarded as wearable robots designed around the shape and function of the human body. A powered exoskeleton, as described in this evidence review, consists of an exoskeleton-like framework worn by a person that includes a power source supplying energy for limb movement. The goal of the powered exoskeleton is to enable people who do not have volitional movement of their lower extremities to bear weight fully while standing, to ambulate over ground, and to ascend and descend stairs.

Systematic Review

A systematic review by Tamburella (2022) qualitatively summarized the effects of the powered exoskeletons: Ekso (n=20 studies), ReWalk (n=14), Indego (n=4), REX (n=2), or HAL (n=1) on walking and on secondary health outcomes in adults with spinal cord injury.^[4] 566 patients across 41 studies were included, and only one study was an RCT. The review assessed the effects of the powered exoskeleton on walking, cardiorespiratory and metabolic responses, spasticity, balance, quality of life, human-robot interaction, robot data, bowel functionality, strength, activities of daily living, neurophysiology, sensory function, bladder functionality, and body composition/bone density. Of the 41 studies, 13 reported different adverse events during

training with Ekso (n=5 studies), ReWalk (n=5), Indego (n=2), and HAL (n=1). The most frequent adverse events were skin lesions, while the less frequent adverse events were extreme fatigue, falls, bone fractures, or muscle strain. The average total number of sessions across the studies ranged from 1 to 55, and 42% of studies performed three sessions per week. Only two studies (both on Ekso) compared powered exoskeleton with other interventions (e.g., conventional physical therapy). In the studies that reported follow-up, follow-up examinations were performed four weeks after the end of treatment (n=3 studies); or after two months (n=1), two to three months (n=1), and 12 to 15 months (n=1). The most investigated domain was walking measured by the 10-meter walking test (n=18 studies) and the six-minute walk test (n=13), followed by cardiorespiratory and metabolic responses. For each outcome, the systematic review reported the data as "significant" if the authors of each included study reported significant changes in their published data. 37% of studies reported significant improvements in walking after powered exoskeleton training, and 13.9% of studies reported significant improvements in cardiorespiratory and metabolic responses. Ekso studies reported significant improvements in almost all outcomes assessed. No studies reached significance for bladder functionality or sensory function improvements. A major limitation of the systematic review was that all included studies were of moderate or low methodological quality, mainly due to poor study design. Other limitations included the small, heterogeneous number of participants; variable dosage of interventions; the absence of control groups and/or follow-up assessments in many studies; and the various parameters adopted in each domain for different types of comparisons. The heterogeneity of outcome measures precluded the ability to make general conclusions on the effects of powered exoskeletons.

Randomized Trials

Xiaomin (2024) published a single blind RCT of 16 SCI patients to assess the effects of a lower limb walking exoskeleton on quality of life and functional independence.^[5] Participants were randomly assigned to either the exoskeleton-assisted walking group (n=8) or a conventional treatment group (n=8). Both groups received conventional rehabilitation, including aerobic exercise and strength training. The exoskeleton group conducted exoskeleton-assisted walking with the AIDER robotic exoskeleton for 40 to 50 minutes, five times per week for eight weeks. The World Health Organization quality of life scale (WHOQOL-BREF) and the Spinal Cord Independence Measure III (SCIM-III) were assessed before and after training and rehabilitation. No significant differences were observed between treatment groups.

A small (n=25) RCT of the Ekso™ device, published by Edwards (2022), compared exoskeleton gait training to standard or no gait training (2:2:1 randomization) for 12 weeks.^[6] There were no significant differences in the primary outcome measure of change in robot-independent gait speed (10-meter walk test, 10MWT) or other secondary outcomes by group.

One small (n=29), randomized, open-label, cross-over study by McGibbon (2018) evaluated the Keeogo™ exoskeleton for patients with multiple sclerosis.^[7] The device was first used in the clinic setting followed by a two-week at-home period. Outcomes were compared with and without the device both in-clinic and at-home. Use of the device initially decreased performance measures during training in the clinic setting, including but these measures did improve after the at-home period.

Case Series

Several case series evaluating various powered exoskeletons for ambulation have been conducted primarily in the inpatient setting for spinal cord injury. Table 1 provides a summary of the characteristics of key case series.

van Dijsseldonk (2020) assessed the use of ReWalk™ Personal 6.0 exoskeleton in the community setting for up to three weeks of use.^[8] Patients used the ReWalk a median of 9 out of 16 days (primarily for exercise) taking a median of 3,226 steps. Overall, the exoskeleton was useful for exercise and social interaction but less useful for assistance with activities of daily living. The mean satisfaction score was 3.7 on a 1 to 5 scale indicating satisfaction with the device.

Bach Baungaard (2018) evaluated robotic exoskeletons from Ekso Bionics® (Ekso and Ekso GT) at nine European rehabilitation centers.^[9] There were no serious adverse events, but three patients withdrew due to overuse injuries and four patients developed pressure ulcers from the device. Initially 20% of patients who were less than one year after injury had gait function without the exoskeleton and this increased to 56% of patients after exoskeleton training ($p=0.004$). In patients who were more than one-year post-injury, 41% had gait function without the exoskeleton at baseline and only one additional patient (for a total of 44%) gained gait function after training.

Tefertiller (2018) evaluated the Indego® device in nonambulatory patients.^[10] Outcomes improved from midpoint of training to the end of training. Indoor walk speed increased from an average of 0.31 m/s at midpoint to 0.37 m/s at final evaluation. The six-minute walk test improved from an average of 92 m to 107.5 m at the final evaluation. A total of 66 adverse events were reported with 11 deemed to be device-related. The adverse events were primarily skin irritation, redness, or bruising due to the device. The Indego® powered exoskeleton was evaluated after five training sessions (lasting 1.5 hours each for five consecutive days) in 16 patients with spinal cord injury between C5 and L1.^[11] Testing included the six-minute walk test and 10-meter walk test. Following training, patients with motor complete tetraplegia (C5-C7 injury level) were able to ambulate on indoor surfaces (hard flooring, carpet, and thresholds), outdoor surfaces (sidewalks), elevators, and ramps, using a walker with assistance from one or two therapists. In the group of patients with upper paraplegia (T1-T8 injury level), all were able to walk on indoor surfaces, outdoor surfaces, and in elevators; and most were successfully tested on ramps. Among the eight patients with lower paraplegia (T9-L1 injury level), six were able to walk without assistance on indoor surfaces, outdoor surfaces, elevators, ramps, and grass, and two required minimal assistance from a therapist.

Esquenazi (2012) published a safety and efficacy trial of the ReWalk™ in 12 subjects with motor complete thoracic spinal cord injury.^[12] All had lower-limb bone and joint integrity, adequate joint range of motion, and a history of standing (either with lower-limb bracing or a standing frame) on a frequent basis. Over eight weeks, subjects received up to 24 sessions of training lasting 60 to 90 minutes per session that included stepping, sit-to-stand, standing, and stand-to-sit transfers. During this time, unsupervised use of the exoskeleton was not allowed. All 12 participants completed training and were able to independently transfer and walk for at least 50 to 100 meters for a period of at least 5 to 10 minutes. Participants did occasionally lose their balance and either caught themselves with their crutches or were stabilized by the physical therapist. With monitoring of walking, there were no serious adverse events such as falls, bone fractures, or episodes of autonomic dysreflexia. Self-reported health benefits collected at the end of training from 11 subjects included reduced spasticity ($n=3$) and improved bowel regulation ($n=5$).

Table 1. Summary of Key Case Series Characteristics

Study	Participants	Treatment	Follow-up
Esquenazi (2012) ^[12]	Adults at least 6 months post motor-complete SCI between C7-T12 (N=12)	ReWalk™	8 weeks of training with follow-up at about 1 year
Hartigan (2015) ^[11]	Adults with SCI ranging from C5 complete to L1 incomplete (N=16)	Indego®	5 training sessions
Bach Baungaard (2018) ^[9]	Patients at least 15 years of age and at least 30 days after spinal cord injury (N=52)	Ekso Bionics®	8 weeks of training
Tefertiller (2018) ^[10]	Nonambulatory adults with SCI T4 and lower (N=32)	Indego®	8 weeks of training
van Dijksseldonk (2020) ^[8]	Adults at least 6 months post motor-complete SCI between T1 and L1 (N=14)	ReWalk™ Personal 6.0 for in-home use after 8 weeks of training	2 to 3 weeks of in-home use

C: cervical; L: lumbar; SCI: spinal cord injury; T: thoracic.

POWERED EXOSKELETON FOR REHABILITATION

Systematic Reviews

Mehrholz (2015) published a Cochrane systematic review and meta-analysis of electromechanical and robot-assisted arm training devices used for rehabilitation after stroke.^[13] The review included 34 RCTs (n=1,160 participants) that compared electromechanical and robot-assisted arm training for recovery of arm function with other rehabilitation or placebo interventions, or no treatment, after stroke. This systematic review included an RCT that compared a hand-sleeve powered exoskeleton for robot-assisted therapy combined with standard physical therapy compared to therapist-assisted repetitive task practice.^[14] Electromechanical and robot-assisted arm training improved activities of daily living scores (standard mean difference [SMD] 0.37, 95% confidence interval [CI] 0.11 to 0.64, p=0.005, I²=62%), arm function (SMD 0.35, 95% CI 0.18 to 0.51, p<0.0001, I²=36%), and arm muscle strength (SMD 0.36, 95% CI 0.01 to 0.70, p=0.04, I²=72%), but the quality of the evidence was low to very low. The authors concluded that electromechanical and robot-assisted arm and hand training after stroke might improve activities of daily living, arm and hand function, and arm and hand muscle strength. However, the results must be interpreted with caution because the quality of the evidence was low to very low, and there were variations between the trials in the intensity, duration, and amount of training; type of treatment; and participant characteristics.

Randomized Controlled Trials

Wolf (2015) investigated the efficacy of home-based telemonitored robotic-assisted therapy with the Motus Hand as part of a home exercise program compared to a dose-matched home exercise program-only intervention in 99 individuals less than six months post-stroke.^[15] The Action Research Arm Test and Wolf Motor Function Test along with the Fugl-Meyer Assessment (UE) were primary and secondary outcome measures, respectively, undertaken before and after the interventions. Both groups demonstrated improvement across all upper extremity outcomes, with no significant difference between the groups in change in motor

function over time. Motus Hand-assisted therapy did not produce results superior to the home exercise group.

Linder (2015) published quality of life and depression outcome results from the same RCT published by Wolf (2015).^[16] Quality of life and depression outcomes were measured after eight weeks of the two interventions. Both groups showed similar improvement in quality of life and depression outcomes. The robot-assisted therapy group did not produce superior results compared to the home exercise group.

Case Reports

Rosenstein (2008) investigated the effect of a robotic device combined with repetitive-task practice on upper-extremity function in a case report of a patient with chronic stroke.^[17] The patient, a 32-year-old woman 11 months post-stroke, received approximately 48 hours of intervention split evenly between a robotic device (Motus Hand Mentor) and repetitive task practice over three weeks. The patient experienced improvements in active range of motion in the shoulder, wrist, and thumb, as well as improved specification of grasping forces for both limbs during a bimanual dexterity task.

SUMMARY OF EVIDENCE

For individuals who have lower-limb disabilities who receive a powered exoskeleton for ambulation, the evidence includes one systematic review, one RCT, one randomized cross-over trial, and several case series. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. At the present, evaluation of exoskeletons is limited to small studies primarily performed in institutional settings with patients who have spinal cord injury. These studies have assessed the user's ability to perform, under close supervision, standard tasks such as the Timed Up & Go test, six-minute walk test, and 10-meter walk test. Further evaluation of users' safety with these devices under regular conditions, including the potential to trip and fall, should be assessed. Further study is needed to determine the benefits of these devices outside of the institutional setting.

For individuals who have lower-limb disabilities who receive a powered exoskeleton for rehabilitation, the evidence includes one systematic review, one RCT, and one case report. Relevant outcomes are functional motor outcomes, quality of life, and treatment-related morbidity. Current evidence for powered exoskeletons for rehabilitation do not show improvements with robotic exoskeleton-assisted physical therapy when compared to standard in-person physical therapy or an at-home exercise program. Additional research is needed to determine the benefits of these devices compared to standard physical therapy and at-home exercise programs.

PRACTICE GUIDELINE SUMMARY

AMERICAN PHYSICAL THERAPY ASSOCIATION

The American Physical Therapy Association published guidelines in 2020 providing recommendations to guide improvement of locomotor function after brain injury, stroke, or incomplete spinal cord injury in ambulatory patients.^[18] The guidelines recommend against the use of powered exoskeletons for use on a treadmill or elliptical to improve walking speed or distance following acute-onset central nervous system injury in patients more than six months post-injury due to minimal benefit and increased costs and time.

SUMMARY

There is not enough research to show that powered exoskeletons for ambulation can improve health outcomes for patient with limited mobility. At the present, evaluation of exoskeletons is limited to small studies performed in institutional settings with patients who have spinal cord injury. There are concerns about users' safety with these devices under regular conditions, including the potential to trip and fall. Further study is needed to determine the benefits of these devices outside of the institutional setting. Therefore, these devices are considered investigational.

There is not enough research to show that powered exoskeletons for rehabilitation can improve health outcomes for stroke patients. Current evidence shows that use of a powered exoskeleton for rehabilitation does not improve health outcomes more than established standard rehabilitation programs and home exercise programs. No evidence-based clinical guidelines recommend powered exoskeletons for rehabilitation. Therefore, these devices are considered investigational.

REFERENCES

1. Zeilig G, Weingarden H, Zwecker M, et al. Safety and tolerance of the ReWalk exoskeleton suit for ambulation by people with complete spinal cord injury: a pilot study. *J Spinal Cord Med.* 2012;35(2):96-101. PMID: 22333043
2. Asselin P, Knezevic S, Kornfeld S, et al. Heart rate and oxygen demand of powered exoskeleton-assisted walking in persons with paraplegia. *J Rehabil Res Dev.* 2015;52:147-58. PMID: 26230182
3. Lajeunesse V, Vincent C, Routhier F, et al. Exoskeletons' design and usefulness evidence according to a systematic review of lower limb exoskeletons used for functional mobility by people with spinal cord injury. *Disability and rehabilitation Assistive technology.* 2016;11(7):535-47. PMID: 26340538
4. Tamburella F, Lorusso M, Tramontano M, et al. Overground robotic training effects on walking and secondary health conditions in individuals with spinal cord injury: systematic review. *Journal of NeuroEngineering and Rehabilitation.* 2022;19(1):27. PMID: 35292044
5. Hu X, Lu J, Wang Y, et al. Effects of a lower limb walking exoskeleton on quality of life and activities of daily living in patients with complete spinal cord injury: A randomized controlled trial. *Technol Health Care.* 2024;32(1):243-53. PMID: 37483030
6. Edwards DJ, Forrest G, Cortes M, et al. Walking improvement in chronic incomplete spinal cord injury with exoskeleton robotic training (WISE): a randomized controlled trial. *Spinal Cord.* 2022;60(6):522-32. PMID: 35094007
7. McGibbon CA, Sexton A, Jayaraman A, et al. Evaluation of the Keeogo exoskeleton for assisting ambulatory activities in people with multiple sclerosis: an open-label, randomized, cross-over trial. *J Neuroeng Rehabil.* 2018;15(1):117. PMID: 30541585
8. van Dijksseldonk RB, van Nes IJW, Geurts ACH, et al. Exoskeleton home and community use in people with complete spinal cord injury. *Sci Rep.* 2020;10(1):15600. PMID: 32973244

9. Bach Baunsgaard C, Vig Nissen U, Katrin Brust A, et al. Gait training after spinal cord injury: safety, feasibility and gait function following 8 weeks of training with the exoskeletons from Ekso Bionics. *Spinal Cord*. 2018;56(2):106-16. PMID: 29105657
10. Tefertiller C, Hays K, Jones J, et al. Initial Outcomes from a Multicenter Study Utilizing the Indego Powered Exoskeleton in Spinal Cord Injury. *Topics in spinal cord injury rehabilitation*. 2018;24(1):78-85. PMID: 29434463
11. Hartigan C, Kandilakis C, Dalley S, et al. Mobility Outcomes Following Five Training Sessions with a Powered Exoskeleton. *Topics in spinal cord injury rehabilitation*. 2015;21(2):93-9. PMID: 26364278
12. Esquenazi A, Talaty M, Packel A, et al. The ReWalk powered exoskeleton to restore ambulatory function to individuals with thoracic-level motor-complete spinal cord injury. *Am J Phys Med Rehabil*. 2012;91:911-21. PMID: 23085703
13. Mehrholz J, Pohl M, Platz T, et al. Electromechanical and robot-assisted arm training for improving activities of daily living, arm function, and arm muscle strength after stroke. *Cochrane Database Syst Rev*. 2015;2015(11):Cd006876. PMID: 26559225
14. Kutner NG, Zhang R, Butler AJ, et al. Quality-of-life change associated with robotic-assisted therapy to improve hand motor function in patients with subacute stroke: a randomized clinical trial. *Phys Ther*. 2010;90(4):493-504. PMID: 20185616
15. Wolf SL, Sahu K, Bay RC, et al. The HAAP (Home Arm Assistance Progression Initiative) Trial: A Novel Robotics Delivery Approach in Stroke Rehabilitation. *Neurorehabil Neural Repair*. 2015;29(10):958-68. PMID: 25782693
16. Linder SM, Rosenfeldt AB, Bay RC, et al. Improving Quality of Life and Depression After Stroke Through Telerehabilitation. *Am J Occup Ther*. 2015;69(2):6902290020p1-10. PMID: 26122686
17. Rosenstein L, Ridgel AL, Thota A, et al. Effects of combined robotic therapy and repetitive-task practice on upper-extremity function in a patient with chronic stroke. *Am J Occup Ther*. 2008;62(1):28-35. PMID: 18254428
18. Hornby TG, Reisman DS, Ward IG, et al. Clinical Practice Guideline to Improve Locomotor Function Following Chronic Stroke, Incomplete Spinal Cord Injury, and Brain Injury. *J Neurol Phys Ther*. 2020;44(1):49-100. PMID: 31834165

CODES

Codes	Number	Description
CPT	None	
HCPCS	E0739	Rehabilitation system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors
	E1399	Durable medical equipment misc
	K1007	Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors

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