

Policy Number	DME103.008
Policy Effective Date	8/18/2026

Powered Exoskeletons

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

Related Policies (if applicable)
DME104.001 Myoelectric Prosthetic and Orthotic Components for the Upper Limb

Disclaimer

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Use of powered exoskeletons, powered upper extremity orthoses, or rehabilitation robots, including but not limited to those used for ambulation in individuals with lower limb disabilities, **is considered experimental, investigational and/or unproven** for all indications.

NOTE 1: This policy does not address the use of orthoses such as a rigid or semi-rigid device used to support or align body parts, prevent or correct deformities, protect a body function, improve or restore the function of movable body parts, or assist a dysfunctional joint.

Policy Guidelines

None.

Description

The goal of the powered exoskeleton is 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. The goal of the powered exoskeleton in the upper extremities is to assist in the assessment and treatment of upper body movement impairment. The devices have the potential to restore mobility and thus, might improve functional status, quality of life, and health status for patients with spinal cord injury, multiple sclerosis, amyotrophic lateral sclerosis, Guillain-Barré syndrome, and spina bifida.

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 policy, consists of an exoskeleton-like framework worn by a person that includes a power source supplying energy for limb movement.

Lower Extremity Exoskeletons

One type of powered lower-limb exoskeleton (e.g., ReWalk®, Indego®) 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 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 5-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 2 seconds, which triggers the safety mechanism to stop

walking. Some patients have become proficient with ReWalk by the third week of training.
(2)

Upper Extremity Powered Orthoses/Exoskeletons

Individuals with neuromuscular disabilities often have trouble using their upper limbs and must rely on assistance from others and/or assistive technology to perform routine functions. An orthosis (or orthotic device) for aiding upper limb movement enables use of the limb in a larger range of motion than can be accomplished independently (50). Choice of orthosis will depend on a number of objective and subjective factors.

Rehabilitation robots and powered orthoses are intended for the weakest Individuals, who in some cases have little to no muscle force (50). They serve as means of increasing training intensity (e.g., number of repetitions) and may allow the Individual to train without a therapist. These devices amplify weak muscle signals from nerve signals on the skin surface to activate arm and/or hand movement, as the user intends. A powered orthosis helps to correct, rehabilitate, or support the limb, whereas a rehabilitation robot works in parallel with the body to assist the user's movements. Current robots tend to train the shoulder and elbow, but devices for improving hand dexterity are emerging that may improve self-reported function and perceptions of overall recovery in stroke survivors (51, 52).

Rehabilitation robots are either end-effector types or exoskeletons depending on the way the limb is supported and moved (53). An end-effector type uses a device connected to the end of a robotic arm (e.g., a gripper where the hand would be) that interacts with the environment as a substitute for limb movement. An example is the MIME (Stanford University). End-effector robots can be easily adapted and used by several Individuals with different pathologies. They provide information about end effector performance that allows the therapist to objectively assess and customize therapy, but they cannot provide kinematic information about the joints of the upper limb (54).

The robotic exoskeleton is a wearable device consisting of a protective and supportive shell with integrated sensor and control information that allows the Individual total control of the arm joints to perform limb movements aided by the robot (53). However, exoskeletons are difficult to adapt and attach to the Individual's arm, as they require meticulous attention to detail to avoid misalignment between the robot and arm and potential injury. Several robotic exoskeletons have been developed for the upper limb. Examples are (53): RUPERT (University of Arizona); the CADEN-77 (University of Washington); the Wilmington robotic exoskeleton (JAECO Orthopedic, 2024); the Armeo Spring (Hocoma Inc., Norwell, Massachusetts); and the MyoPro® (Myomo, Inc., Cambridge, Massachusetts, 2024).

NOTE 2: The MyoPro® orthotic device is addressed in DME104.001 Myoelectric Prosthetic and Orthotic Components for the Upper Limb.

Regulatory Status

Lower Extremity Exoskeletons

In 2014, ReWalk (LIFEWARD, previously Argo Medical Technologies and ReWalk Robotics) 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 (current version ReWalk 7) 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 adult (≥ 18 years old) 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.

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" to 6'3"); and
- 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. Ekso Bionics acquired Indego in 2022.

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, and individuals with spinal cord injuries at levels of C7 to T3. Ekso Indego Personal is intended for home use.

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 (American Spinal Injury Association [ASIA] Impairment Scale C, ASIA D) and T11 to L5 (ASIA A with Zones of Partial Preservation, ASIA B). HAL for Medical Use (K233695) has expanded indications for post stroke paresis, paraplegia due to neuromuscular diseases, cerebral palsy, and spastic paraplegia.

In 2020, Keeego™ (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. Keeego is intended for use in patients with stroke 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 1 person.

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 1 arm); individuals with acquired brain injury, including traumatic brain injury and stroke (upper extremity motor function of at least 4/5 in at least 1 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 2022, Atalante® (Wandercraft SAS; current version Atalante X) was cleared for marketing by the FDA through the 510(k) process (K221859). The Indego was the predicate device.

Atalante is intended to enable individuals (>18 years of age, able to tolerate a stand-up position) with hemiplegia due to cerebrovascular accident 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 C4 to L5, and individuals with multiple sclerosis.

FDA product code: PHL.

Upper Extremity Powered Orthoses/Exoskeletons

In 2017, the FDA approved the Wilmington robotic exoskeleton (WREX) UAECO Orthopedic) as a class I medical device. The WREX is a passive, body-powered, antigravity arm orthosis designed to enhance movement for individuals with neuromuscular disabilities of the upper extremity. Modifications to the WREX include the now commercialized Armeo Spring, formerly known as the Therapy Wilmington Robotic Exoskeleton (T-WREX) (Biorobotics Laboratory). The FDA classifies the Armeo Spring as a Class II device. This device is aimed at those with weakened hands, to practice using their hands in a virtual world via computer games with simulated movements.

In 2019, Ekso Bionics Holdings, Inc announced the EksoUE™, an upper extremity rehabilitation device. The wearable upper body exoskeleton is put on similar to a jacket, secured at the waist, and on the arms and wrists. Lift assistance is provided by passive mechanisms located on the arms. EksoUETM is registered with the FDA as a class I medical device.

In 2020, the FDA approved the Abilitech® Assist (Abilitech Medical) as a class I medical device. The Abilitech® Assist is an arm support device developed for patients with arm weakness or injury, specifically neuromuscular weakness, to complete activities of daily living. The device provides a hybrid assist at the shoulder and elbow and includes springs at the shoulder and elbow and a connected battery pack to assist with movement.

Rationale

Pre-post study designs (using patients as their own controls) 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

The purpose of a powered exoskeleton for ambulation is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with lower limb disabilities. The goal of the powered exoskeleton is to enable individuals 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.

Review of Evidence

There is limited information about the use of powered exoskeletons outside of the institutional setting. Standard measures of walking function include the Timed Up-and-Go test, which assesses the time required to get up from a chair and commence walking; the 10-meter walk test, which evaluates the time required to walk 10 meters; and the 6-minute walk test, which measures the distance walked in 6 minutes. A less used test, the timed stair test, evaluates the time it takes to ascend or descend 10 stairs and has been used in powered exoskeleton studies.

Systematic Review

A systematic review by Tamburella et al. (2022) qualitatively summarized the effects of the powered exoskeleton (Ekso, ReWalk, Indego, REX, or HAL) on walking and on secondary health outcomes in patients with spinal cord injury. (4) A total of 41 studies (566 patients) were included, of which only 1 was an RCT (Table 1). The characteristics of the systematic review are summarized in Table 2. The average patient age was 43.58 ± 7.84 years. The study assessed the effects of the powered exoskeleton on 14 domains: walking, cardiorespiratory/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. The effects of Ekso, ReWalk, Indego, REX, and HAL were analyzed in 20, 14, 4, 2, and 1 studies, respectively. 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 3 sessions per week. Only 2 studies (both on Ekso) compared powered exoskeleton with other interventions (i.e., conventional physical therapy). In the studies that reported follow-up, follow-up examinations were performed 4 weeks after the end of treatment (n=3); or after 2 months (n=1), 2 to 3 months (n=1), and 12 to 15 months (n=1). Table 3 summarizes the

results of the systematic review. Most studies used outcome measures relating to the walking domain; walking velocity was measured per the 10-meter walking test in 18 studies and the 6-minute walk test in 13 studies. For each domain, the systematic review reported the data as "significant" if the authors of each included study reported significant changes in their published data. A major limitation of the systematic review was that all included studies were of moderate or low methodological quality level, 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.

Table 1. Studies Included in the Systematic Review

Study	Tamburella et al. (2022) (4)
Chun et al. (2020) (5)	●
McIntosh et al. (2020) (6)	●
Tsai et al. (2020) (7)	●
Gagnon et al. (2019) (8)	●
Guanziroli et al. (2019) (9)	●
Khan et al. (2019) (10)	●
Kressler et al. (2019) (11)	●
Kubota et al. (2019) (12)	●
Manns et al. (2019) (13)	●
van Dijsseldonk et al. (2019) (14)	●
Alamro et al. (2018) (15)	●
Bach Baunsgaard et al. (2018) (16)	●
Baunsgaard et al. (2018) (17)	●
Cahill et al. (2018) (18)	●
Chang et al. (2018) (19)	●
Escalona et al. (2018) (20)	●
Gagnon et al. (2018) (21)	●
Juszczak et al. (2018) (22)	●
Ramanujam et al. (2018) (23)	●
Ramanujam et al. (2018) (24)	●
Sale et al. (2018) (25)	●
Tefertiller et al. (2018) (26)	●
Yatsugi et al. (2018) (27)	●
Birch et al. (2017) (28)	●
Karelis et al. (2017) (29)	●
Benson et al. (2016) (30)	●
Lonini et al. (2016) (31)	●
Platz et al. (2016) (32)	●

Sale et al. (2016) (33)	●
Stampacchia et al. (2016) (34)	●
Kozlowski et al. (2015) (35)	●
Asselin et al. (2015) (2)	●
Evans et al. (2015) (36)	●
Hartigan et al. (2015) (37)	●
Yang et al. (2015) (38)	●
Kressler et al. (2014) (39)	●
Fineberg et al. (2013) (40)	●
Kolakowsky-Hayner et al. (2013) (41)	●
Talaty et al. (2013) (42)	●
Esquenazi et al. (2012) (43)	●
Zeilig et al. (2012) (1)	●

Table 2. Systematic Review Characteristics

Study	Dates	Trials	Participants ¹	N (Range)	Design	Duration
Tamburella et al. (2022) (4)	2012-2020	41	Patients >18 years of age with SCI using powered exoskeleton (Ekso, ReWalk, Indego, REX or HAL)	566 (2 to 52)	RCTs (parallel-group or cross-over design) and non-randomized trials (cohort studies, case-control, case series, pilot studies)	NR

¹Trials of patients affected by spinal cord injury and other neurological conditions (e.g., multiple sclerosis, stroke) were also included if at least 50% of participants were affected by a spinal cord injury.

NR: not reported; RCT: randomized controlled trial; SCI: spinal cord injury.

Table 3. Systematic Review Results

Study	% of Studies Addressing Each Domain	% of Studies with ≥1 Outcome Measure for Each Domain with Significant Improvements After Powered Exoskeleton Training
Tamburella et al. (2022) (4)		
<i>Domains</i>		
Walking	27	37.2
Cardiorespiratory and metabolic responses	16	13.9

Spasticity	14	6.9
Balance	12	6.9
QOL	12	6.9
Strength	6	6.9
ADL	5	6.9
Human-robot interaction	9	4.6
Robot data	8	3.8
Neurophysiology	4	3.8
Body composition and body density	1	3.8
Bowel functionality	8	2.3
Sensory function	2	0
Bladder function	2	0

ADL: activities of daily living; QOL: quality of life.

Randomized Controlled Trial

An RCT (The Veterans Health Administration Cooperative Studies Program: Powered Exoskeletons for Persons with Spinal Cord Injury [PEPSCI] Trial) was designed for the study of exoskeletal-assisted walking in the home and community environments in patients with chronic spinal cord injury. (44, 45) Of 424 enrolled patients, 263 failed screening and were not randomized. Of the 161 randomized patients, 151 (93.8%) were male; the mean age (interquartile range) was 47 (35 to 56) years. The intervention group consisted of standard of care (wheelchair for mobility) and use of ReWalk 6.0 exoskeleton at home for 4 months, while the control group consisted of standard of care (wheelchair) only. The primary aims of the study were to demonstrate clinically meaningful net improvements in the Mental Component Summary of the Veterans Rand-36 (MCS/VR-36) and in patient-reported outcomes for the Spinal Cord Injury Quality of Life (SCI-QOL) assessment tool for the physical-medical health domain components of bladder, bowel, and pain item banks. The major secondary aim was to demonstrate a reduction in total body fat mass. Tables 4 and 5 provide a summary of the characteristics and results of the study. Limitations of the RCT include extensive exclusion criteria (resulting in several patients failing the screening process); furthermore, the use of an exoskeleton as an intervention prevented the ability for single- or double-blinding.

Table 4. Summary of Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions (N=61)	
					Active (n=78)	Comparator (n=83)
Spungen et al. (2020) (44, 45);	U.S.	15	2016-2021	Veterans or active duty military	ReWalk Personal 6.0	Wheelchair only

NCT02658656				personnel ≥ 18 years of age • With traumatic or non-traumatic SCI of 6 months duration • Using a wheelchair for indoor and outdoor mobility	exoskeleton (in-home use for 4 months) + wheelchair	
-------------	--	--	--	---	---	--

NCT: national clinical trial; SCI: spinal cord injury; U.S.: United States.

Table 5. Summary of Randomized Controlled Trial Results

Study	No. (%) of Patients with ≥ 4 -Point Change on the MSC/VR-36 from Baseline to 4 Months Post Intervention ¹	No. (%) of Patients with $\geq 10\%$ Decrease on the SCI-QOL PMH Domain from Baseline to 4 Months Post Intervention ²	No. (%) of Patients with ≥ 1 kg of Total Body Fat Loss from Baseline to 4 Months Post Intervention ³	No. (%) of Patients with Serious Adverse Events
Spungen et al. (2020) (44, 45); NCT02658656				
ReWalk Personal 6.0 + wheelchair	12 (15.4)	10 (12.8)	14 (17.9)	12 (15.4)
Wheelchair	14 (16.9)	11 (13.3)	16 (19.3)	14 (16.9)
RR	0.91	0.97	0.93	
95% CI	0.45 to 1.85	0.44 to 2.15	0.49 to 1.78	
p-value	0.80	0.949	0.83	

¹ Possible range of the MCS/VR-36 is 0 to 100, with a higher score indicating higher mental well-being.

² The PMH score is a sum of the SCI-QOL scores from the Bladder Management Difficulties, Bowel Management Difficulties, and Pain Interference item banks; possible range of the PMH score is 110 to 253, with a lower score indicating better physical medical well-being.

³ Measured by dual photon x-ray absorptiometry (DXA) scan.

CI: confidence interval; kg: kilogram; MCS/VR-36: Mental Health Component Summary of

the Veterans Rand-36; NCT: national clinical trial; No: number; PMH: Physical Medical Health; RR: risk ratio; SCI-QOL: Spinal Cord Injury Quality of Life.

Randomized Crossover Trial

One small (N=29), randomized, open-label, cross-over study evaluated the Keeogo exoskeleton for patients with multiple sclerosis. (46) The device was first used in the clinic setting followed by a 2-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, but these measures did improve after the at-home period. Tables 6 and 7 provide a summary of the characteristics and results of this trial.

Table 6. Summary of Cross-Over Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions (N=29)	
					Active	Comparator
McGibbon et al. (2018) (46)	U.S., Canada	4	2015-2017	- Ambulatory adults with MS - Able to walk at least 25 m using assisted devices as needed without human assistance	Keeogo exoskeleton	No exoskeleton

MS: multiple sclerosis; m: meters; U.S.: United States.

Table 7. Summary of Cross-over Trial Results

Study	6-Minute Walk Test (Mean [SD]) ¹	Timed Up-and-Go (Mean [SD]) ¹	Timed Stair Test-Up (Mean [SD]) ¹	Timed Stair Test-Down (Mean [SD]) ¹	Mean Steps per Day (SD) ²
McGibbon et al. (2018) (46)	N=29	N=29	N=29	N=29	N=29
Exoskeleton	236.8 m (100.6)	20.5 s (7.5)	17.6 s (8.8)	13.1 s (7.0)	4693.5 (2996.0)
No exoskeleton	259.5 m (100.7)	16.2 s (5.8)	12.7 s (5.9)	15.7 s (7.7)	4425.1 (2897.0)
Change (p-value)	-22.7 (.001)	4.3 (<.001)	4.8 (<.001)	2.6 (.002)	268.4 (.046)

¹ In the clinic setting.

² In the home setting.

SD: standard deviation; m: meters; s: seconds.

Case Series

Several case series evaluating various powered exoskeletons for ambulation have been conducted primarily in the inpatient setting for spinal cord injury. These case series were included in the systematic review by Tamburella et al. (2022) discussed earlier.

One case series has been conducted to assess the use of the powered exoskeleton in the community setting. van Dijksseldonk et al. (2020) assessed the use of the ReWalk Personal 6.0 exoskeleton in the community setting for up to 3 weeks of use. (47) Table 8 summarizes the characteristics of this study. Patients used the ReWalk a median of 9 out of 16 days (primarily for exercise) taking a median of 3226 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 scale of 1 to 5 indicating satisfaction with the device.

Table 8. Summary of Key Case Series Characteristics

Study	Country	Participants	Treatment	Follow-up
van Dijksseldonk et al. (2020) (47)	The Netherlands	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

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

Section Summary: Powered Exoskeleton for Ambulation

Several small studies have evaluated the use of powered exoskeletons for ambulation in individuals with spinal cord injury in the institutional setting. These studies were included in a recently published systematic review that summarized the effects of the powered exoskeleton on walking, quality of life, and other secondary health conditions; however, the heterogeneity of outcome measures hindered authors from making general conclusions. One RCT, a randomized crossover study, and a case series have assessed the use of powered exoskeletons in the home/community setting. Although these studies indicate that powered exoskeletons may be used safely in the outpatient setting, further research is necessary to assess efficacy and safety of the technology. High-quality, comparative studies are needed to determine the benefits of powered exoskeletons for ambulation both in institutional and community settings.

Upper Extremity Powered Orthoses/Exoskeletons

Systematic reviews

Evidence regarding the comparative effectiveness of robotic devices versus standard care and their impact on activities of daily living remains unfavorable or mixed. One multisite trial carried out in the United Kingdom (n =770) found that robot-assisted training did not

improve upper limb function success, measured by the Action Research Arm Test at three months, compared with usual care or an enhanced therapy protocol for participants with moderate or severe impairment (55). Newer systematic reviews indicate that robotic rehabilitation does not result in significant differences in the performance of activities of daily living compared to conventional rehabilitation either immediately post-treatment or at follow-up (56). While one review noted a small, statistically significant positive effect on upper limb capacity immediately following intervention, these gains were not maintained at follow-up assessments (56). Other randomized or quasi-randomized controlled trials reported mixed results regarding the superiority of robotic protocols (57, 58, 59).

The comparative effectiveness of robotic therapy may depend on device characteristics, treatment dose, and participant selection. Subgroup analyses suggest that devices that allow for partial assistance, where the user actively contributes to movement, may yield better results than those providing full assistance. Furthermore, targeting the distal upper limb may be more effective than proximal training (56). Additionally, portable rehabilitation robots have demonstrated effectiveness in improving upper limb function compared to non-robotic therapy in a smaller subset of trials ($n = 295$), suggesting feasibility for portable designs (60). Regarding timing, the effectiveness of the intervention may be influenced by the recovery phase and duration of treatment (61, 62).

Reviews of specific anatomic locations and non-stroke populations provide limited support for these interventions. For hand and finger function specifically, randomized controlled trials found some improvement in motor function with a robotic adjunct, but conclusions are limited by small sample sizes, variations in devices, and inconsistent protocols (63-67). In participants with cervical spinal cord injury, a systematic review of one randomized clinical trial and several case series suggests robot-assisted interventions are safe and feasible and may reduce the active assistance provided by therapists, but the optimal device and training protocol remain undefined (68). Finally, in children with cerebral palsy, limited results from case studies and small observational studies suggest a moderate improvement in reaching duration, smoothness, or decreased muscle tone (69).

Meta analysis

Recent large-scale evidence reviews have focused heavily on distinguishing between statistical significance and clinical relevance regarding robotic therapy for stroke rehabilitation. An umbrella review of 16 meta-analyses ($n = 19,280$) and a re-analysis of randomized controlled trials found that while robot-assisted therapy produced statistically significant improvements in motor recovery compared to conventional therapy, the magnitude of these improvements failed to meet the established thresholds for the minimal clinically important difference in both subacute and chronic stroke populations (70). This finding is corroborated by a separate metaanalysis ($n = 3,452$) which concluded that although robotic training showed statistically significant effects on dexterity, strength, and arm function, none of these domains achieved clinical relevance when compared to control groups (71).

Further analysis questions the generalization of motor gains to functional capacity. A large review of 90 trials (n= 4,311) determined that the small significant effects observed at the level of motor impairment did not generalize to clinically meaningful effects regarding upper limb capacity (72). A Cochrane review of 45 trials (n= 1,619) rated as high quality similarly found that electromechanical and robot-assisted arm training devices were safe and acceptable to most participants and modestly improved arm function and muscle strength. However, it remained unclear if these slight improvements were clinically meaningful to most participants, and due to heterogeneity in trial designs, the optimal therapeutic intensity could not be determined (73).

Summary of Evidence

Lower Extremity Exoskeletons

For individuals who have lower-limb disabilities who receive a powered exoskeleton, the evidence includes 1 systematic review, 1 randomized controlled trial (RCT), 1 randomized crossover study and 1 case series describing community use. 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, 6-minute walk test, and 10-meter walk test. A recent systematic review included these studies and qualitatively described the effects of powered exoskeletons on walking and on secondary health conditions. However, lack of high-quality studies and heterogeneity of outcome measures precluded the ability to make general conclusions. Evidence on the use of powered exoskeletons in the community or home setting is even more limited. A recent RCT compared quality of life measures in patients with spinal cord injury using in-home powered exoskeleton plus wheelchair versus wheelchair alone and reported similar results between both groups. In addition, 1 randomized, open-label crossover study and a case series in patients with multiple sclerosis and spinal cord injury, respectively, assessed use of powered exoskeletons in the outpatient setting. Although these small studies indicate powered exoskeletons may be used safely in the outpatient setting, these devices require significant training, and their efficacy has been minimally evaluated. Further evaluation of users' safety with these devices under regular conditions, including the potential to trip and fall, is necessary. Additional studies, particularly high-quality RCTs, are needed to determine the benefits of these devices both inside and outside of the institutional setting. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Upper Extremity Powered Orthoses/Exoskeletons

For individuals who need upper extremity powered orthoses/exoskeletons, the literature includes systematic review and meta-analyses. One multisite trial carried out in the United Kingdom (n =770) found that robot-assisted training did not improve upper limb function success compared with usual care or an enhanced therapy protocol for participants with

moderate or severe impairment. Newer systematic reviews indicate that robotic rehabilitation does not result in significant differences in the performance of activities of daily living compared to conventional rehabilitation either immediately post-treatment or at follow-up. An umbrella review of 16 meta-analyses (n= 19,280) and a re-analysis of randomized controlled trials found that while robot-assisted therapy produced statistically significant improvements in motor recovery compared to conventional therapy, the magnitude of these improvements failed to meet the established thresholds for the minimal clinically important difference in both subacute and chronic stroke populations. Additional studies, particularly high-quality RCTs, are needed to determine the benefits of these devices both inside and outside of the institutional setting. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

Lower Extremity Exoskeletons

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. (48) 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 6 months post-injury due to minimal benefit and increased costs and time.

A 2022 article by Hohl et al. comments on how this guideline recommendation adds uncertainty to the clinical application of powered exoskeletons in rehabilitation. (49) Several studies referenced in the guideline did not use the Food and Drug Administration (FDA)-approved devices discussed in this review; rather, the guideline focused on treadmill-based robots, specifically the Lokomat®. Therefore, the conclusions should be interpreted with caution, given the substantial differences in functionality and physical demand between the treadmill-based robots and the powered exoskeletons of interest. Taking into consideration the limited guidance on proper use of powered exoskeletons, Hohl et al. developed a framework for clinical utilization of powered exoskeletons in rehabilitation settings. The aims of the framework are to: 1) assist practitioners with clinical decision making of when exoskeleton use is clinically indicated, 2) help identify which device is most appropriate based on patient deficits and device characteristics, 3) provide guidance on dosage parameters within a plan of care, and 4) provide guidance for reflection following utilization. The framework focuses specifically on clinical application, not use of powered exoskeletons for personal mobility.

Upper Extremity Powered Orthoses/Exoskeletons

Department of Veterans Affairs and Department of Defense

The Department of Veterans Affairs and Department of Defense (2024) (74) updated their guideline on the management of stroke rehabilitation. There is insufficient evidence to

recommend for or against robot-assisted therapy to improve upper extremity motor outcomes based on systematic review evidence showing that the short-term improvements in upper limb movements, as measured by Fugl-Meyer Assessment, only slightly outweighed the potential harms, which were considered minimal and related to discomfort from the harnesses and skin integrity issues.

National Institute for Health and Care Excellence (NICE)

Updated clinical guidelines from the United Kingdom, published in 2023, provide recommendations regarding the use of robotic technology in stroke recovery. The National Institute for Health and Care Excellence (NICE) explicitly recommends against offering robot-assisted arm training as part of an upper limb rehabilitation program (75).

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 9.

Table 9. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06765070	Efficacy and Usability of the EXPLORER Exoskeleton in Children With Neurodevelopmental Disorders in Their Natural Environment	15	Dec 2025
NCT07159360	Safety, Usability, and Effectiveness of a Gait Exoskeleton for Children and Adolescents With Neurodevelopmental Disorders	60	Jun 2026
NCT06921551	Exploratory Pilot Study on the Prolonged Use of the ABLE Exoskeleton in Multiple Sclerosis	20	May 2026
NCT05187650	Effectiveness of a Powered Exoskeleton Combined With Functional Electric Stimulation for Patients With Chronic Spinal Cord Injury: a Randomized Controlled Trial	34	Dec 2025 (recruiting)
NCT01701388	Investigational Study of the Ekso Powered Exoskeleton for Ambulation in Individuals With Spinal Cord Injury (or Similar Neurological Weakness)	40	Dec 2025 (active, not recruiting)
NCT04786821	Feasibility Study for a Randomised Control Trial for the Acceptability of	24	Oct 2024 (recruiting;

	Exoskeleton Assisted Walking Compared to Standard Exercise Training for Persons With Mobility Issues Due to Multiple Sclerosis		last updated May 2024)
--	--	--	------------------------

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	E0739, E1399, K1007, L2999

*Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.

References

Lower Extremity Exoskeletons

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. Mar 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(2):147-158. 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. Disabil Rehabil Assist Technol. Oct 2016; 11(7):535-547. 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. J Neuroeng Rehabil. Mar 15 2022; 19(1):27. PMID 35292044

5. Chun A, Asselin PK, Knezevic S, et al. Changes in bowel function following exoskeletal-assisted walking in persons with spinal cord injury: an observational pilot study. *Spinal Cord*. Apr 2020; 58(4):459-466. PMID 31822808
6. McIntosh K, Charbonneau R, Bensaada Y, et al. The Safety and Feasibility of Exoskeletal-Assisted Walking in Acute Rehabilitation After Spinal Cord Injury. *Arch Phys Med Rehabil*. Jan 2020; 101(1):113-120. PMID 31568761
7. Tsai CY, Delgado AD, Weinrauch WJ, et al. Exoskeletal-Assisted Walking During Acute Inpatient Rehabilitation Leads to Motor and Functional Improvement in Persons With Spinal Cord Injury: A Pilot Study. *Arch Phys Med Rehabil*. Apr 2020; 101(4):607-612. PMID 31891715
8. Gagnon DH, Vermette M, Duclos C, et al. Satisfaction and perceptions of long-term manual wheelchair users with a spinal cord injury upon completion of a locomotor training program with an overground robotic exoskeleton. *Disabil Rehabil Assist Technol*. Feb 2019; 14(2):138-145. PMID 29256640
9. Guanziroli E, Cazzaniga M, Colombo L, et al. Assistive powered exoskeleton for complete spinal cord injury: correlations between walking ability and exoskeleton control. *Eur J Phys Rehabil Med*. Apr 2019; 55(2):209-216. PMID 30156088
10. Khan AS, Livingstone DC, Hurd CL, et al. Retraining walking over ground in a powered exoskeleton after spinal cord injury: a prospective cohort study to examine functional gains and neuroplasticity. *J Neuroeng Rehabil*. Nov 21 2019; 16(1):145. PMID 31752911
11. Kressler J, Domingo A. Cardiometabolic Challenges Provided by Variable Assisted Exoskeletal Versus Overground Walking in Chronic Motor-incomplete Paraplegia: A Case Series. *J Neurol Phys Ther*. Apr 2019; 43(2):128-135. PMID 30883500
12. Kubota S, Abe T, Kadone H, et al. Hybrid assistive limb (HAL) treatment for patients with severe thoracic myelopathy due to ossification of the posterior longitudinal ligament (OPLL) in the postoperative acute/subacute phase: A clinical trial. *J Spinal Cord Med*. Jul 2019; 42(4):517-525. PMID 30335588
13. Manns PJ, Hurd C, Yang JF. Perspectives of people with spinal cord injury learning to walk using a powered exoskeleton. *J Neuroeng Rehabil*. Jul 19 2019; 16(1):94. PMID 31324256
14. van Dijksseldonk RB, Rijken H, van Nes IJW, et al. Predictors of exoskeleton motor learning in spinal cord injured patients. *Disabil Rehabil*. Jul 2021; 43(14):1982-1988. PMID 31724882
15. Alamro RA, Chisholm AE, Williams AMM, et al. Overground walking with a robotic exoskeleton elicits trunk muscle activity in people with high-thoracic motor-complete spinal cord injury. *J Neuroeng Rehabil*. Nov 20 2018; 15(1):109. PMID 30458839
16. 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*. Feb 2018; 56(2):106-116. PMID 29105657
17. Baunsgaard CB, Nissen UV, Brust AK, et al. Exoskeleton gait training after spinal cord injury: An exploratory study on secondary health conditions. *J Rehabil Med*. Sep 28 2018; 50(9):806-813. PMID 30183055

18. Cahill A, Ginley OM, Bertrand C, et al. Gym-based exoskeleton walking: A preliminary exploration of non-ambulatory end-user perspectives. *Disabil Health J.* Jul 2018; 11(3):478-485. PMID 29500092
19. Chang SH, Afzal T, Berliner J, et al. Exoskeleton-assisted gait training to improve gait in individuals with spinal cord injury: a pilot randomized study. *Pilot Feasibility Stud.* 2018; 4:62. PMID 29556414
20. Escalona MJ, Brosseau R, Vermette M, et al. Cardiorespiratory demand and rate of perceived exertion during overground walking with a robotic exoskeleton in long-term manual wheelchair users with chronic spinal cord injury: A cross-sectional study. *Ann Phys Rehabil Med.* Jul 2018; 61(4):215-223. PMID 29371106
21. Gagnon DH, Escalona MJ, Vermette M, et al. Locomotor training using an overground robotic exoskeleton in long-term manual wheelchair users with a chronic spinal cord injury living in the community: Lessons learned from a feasibility study in terms of recruitment, attendance, learnability, performance and safety. *J Neuroeng Rehabil.* Mar 01 2018; 15(1):12. PMID 29490678
22. Juszczak M, Gallo E, Bushnik T. Examining the Effects of a Powered Exoskeleton on Quality of Life and Secondary Impairments in People Living With Spinal Cord Injury. *Top Spinal Cord Inj Rehabil.* 2018; 24(4):336-342. PMID 30459496
23. Ramanujam A, Cirnigliaro CM, Garbarini E, et al. Neuromechanical adaptations during a robotic powered exoskeleton assisted walking session. *J Spinal Cord Med.* Sep 2018; 41(5):518-528. PMID 28427305
24. Ramanujam A, Momeni K, Husain SR, et al. Mechanisms for improving walking speed after longitudinal powered robotic exoskeleton training for individuals with spinal cord injury. *Annu Int Conf IEEE Eng Med Biol Soc.* Jul 2018; 2018:2805-2808. PMID 30440984
25. Sale P, Russo EF, Scarton A, et al. Training for mobility with exoskeleton robot in spinal cord injury patients: a pilot study. *Eur J Phys Rehabil Med.* Oct 2018; 54(5):745-751. PMID 29517187
26. Tefertiller C, Hays K, Jones J, et al. Initial Outcomes from a Multicenter Study Utilizing the Indego Powered Exoskeleton in Spinal Cord Injury. *Top Spinal Cord Inj Rehabil.* 2018; 24(1):78-85. PMID 29434463
27. Yatsugi A, Morishita T, Fukuda H, et al. Feasibility of Neurorehabilitation Using a Hybrid Assistive Limb for Patients Who Underwent Spine Surgery. *Appl Bionics Biomech.* 2018; 2018:7435746. PMID 30116296
28. Birch N, Graham J, Priestley T, et al. Results of the first interim analysis of the RAPPER II trial in patients with spinal cord injury: ambulation and functional exercise programs in the REX powered walking aid. *J Neuroeng Rehabil.* Jun 19 2017; 14(1):60. PMID 28629390
29. Karelis AD, Carvalho LP, Castillo MJ, et al. Effect on body composition and bone mineral density of walking with a robotic exoskeleton in adults with chronic spinal cord injury. *J Rehabil Med.* Jan 19 2017; 49(1):84-87. PMID 27973679
30. Benson I, Hart K, Tussler D, et al. Lower-limb exoskeletons for individuals with chronic spinal cord injury: findings from a feasibility study. *Clin Rehabil.* Jan 2016; 30(1):73-84. PMID 25761635

31. Lonini L, Shawen N, Scanlan K, et al. Accelerometry-enabled measurement of walking performance with a robotic exoskeleton: a pilot study. *J Neuroeng Rehabil.* Mar 31 2016; 13:35. PMID 27037035
32. Platz T, Gillner A, Borgwaldt N, et al. Device-Training for Individuals with Thoracic and Lumbar Spinal Cord Injury Using a Powered Exoskeleton for Technically Assisted Mobility: Achievements and User Satisfaction. *Biomed Res Int.* 2016; 2016:8459018. PMID 27610382
33. Sale P, Russo EF, Russo M, et al. Effects on mobility training and de-adaptations in subjects with Spinal Cord Injury due to a Wearable Robot: a preliminary report. *BMC Neurol.* Jan 28 2016; 16:12. PMID 26818847
34. Stampacchia G, Rustici A, Bigazzi S, et al. Walking with a powered robotic exoskeleton: Subjective experience, spasticity and pain in spinal cord injured persons. *NeuroRehabilitation.* Jun 27 2016; 39(2):277-283. PMID 27372363
35. Kozlowski AJ, Bryce TN, Dijkers MP. Time and Effort Required by Persons with Spinal Cord Injury to Learn to Use a Powered Exoskeleton for Assisted Walking. *Top Spinal Cord Inj Rehabil.* 2015; 21(2):110-121. PMID 26364280
36. Evans N, Hartigan C, Kandilakis C, et al. Acute Cardiorespiratory and Metabolic Responses During Exoskeleton-Assisted Walking Overground Among Persons with Chronic Spinal Cord Injury. *Top Spinal Cord Inj Rehabil.* 2015; 21(2):122-132. PMID 26364281
37. Hartigan C, Kandilakis C, Dalley S, et al. Mobility Outcomes Following Five Training Sessions with a Powered Exoskeleton. *Top Spinal Cord Inj Rehabil.* 2015; 21(2):93-99. PMID 26364278
38. Yang A, Asselin P, Knezevic S, et al. Assessment of In-Hospital Walking Velocity and Level of Assistance in a Powered Exoskeleton in Persons with Spinal Cord Injury. *Top Spinal Cord Inj Rehabil.* 2015; 21(2):100-109. PMID 26364279
39. Kressler J, Thomas CK, Field-Fote EC, et al. Understanding therapeutic benefits of overground bionic ambulation: exploratory case series in persons with chronic, complete spinal cord injury. *Arch Phys Med Rehabil.* Oct 2014; 95(10):1878-1887.e4. PMID 24845221
40. Fineberg DB, Asselin P, Harel NY, et al. Vertical ground reaction force-based analysis of powered exoskeleton-assisted walking in persons with motor-complete paraplegia. *J Spinal Cord Med.* Jul 2013; 36(4):313-321. PMID 23820147
41. Kolakowsky-Hayner SA, Crew J, Morgan S, et al. Safety and Feasibility of using the Ekso™ Bionic Exoskeleton to Aid Ambulation after Spinal Cord Injury. *J Spine.* 2013; 4:456.
42. Talaty M, Esquenazi A, Briceno JE. Differentiating ability in users of the ReWalk™ powered exoskeleton: an analysis of walking kinematics. *IEEE Int Conf Rehabil Robot.* Jun 2013; 2013:6650469. PMID 24187286
43. 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.* Nov 2012; 91(11):911-921. PMID 23085703

44. Spungen AM, Bauman WA, Biswas K, et al. 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. *Contemp Clin Trials*. Sep 2020; 96:106102. PMID 32800962
45. Spungen AM, Dematt EJ, Biswas K, et al. Exoskeletal-Assisted Walking in Veterans With Paralysis: A Randomized Clinical Trial. *JAMA Netw Open*. Sep 3 2024; 7(9):e2431501. PMID 39230903
46. 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*. Dec 12 2018; 15(1):117. PMID 30541585
47. van Dijksseldonk RB, van Nes IJW, Geurts ACH, et al. Exoskeleton home and community use in people with complete spinal cord injury. *Sci Rep*. Sep 24 2020; 10(1):15600. PMID 32973244
48. 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*. Jan 2020; 44(1):49-100. PMID 31834165
49. Hohl K, Giffhorn M, Jackson S, et al. A framework for clinical utilization of robotic exoskeletons in rehabilitation. *J NeuroEngineering Rehabil*. Oct 29 2022; 19(1):115. PMID 36309686

Upper Extremity Powered Orthoses/Exoskeletons

50. Herder JL, Vrijlandt N, Antonides T, et al. Principle and design of a mobile arm support for people with muscular weakness. *J Rehabil Res Dev*. 2006; 43(5):591-604. PMID 17123201
51. Peters HT, Page SJ, Persch A. Giving them a hand: Wearing a myoelectric elbow-wrist-hand orthosis reduces upper extremity impairment in chronic stroke. *Arch Phys Med Rehabil*. 2017; 98(9):1821-1827. PMID 28130084
52. Willigenburg NW, McNally MP, Hewett TE, et al. Portable myoelectric brace use increases upper extremity recovery and participation but does not impact kinematics in chronic, poststroke hemiparesis. *J Mot Behav*. 2017; 49(1):46-54. PMID 27749154
53. Zhang K, Chen X, Liu F, et al. System framework of robotics in upper limb rehabilitation on poststroke motor recovery. *Behav Neurol*. 2018 Dec 13;2018:6737056. PMID 30651892
54. Bertomeu-Motos A, Blanco A, Badesa FJ, et al. Human arm joints reconstruction algorithm in rehabilitation therapies assisted by end-effector robotic devices. *J Neuroeng Rehabil*. 2018; 15(1):10. PMID 29458397
55. Rodgers H, Bosomworth H, Krebs HI, et al. Robot assisted training for the upper limb after stroke (RATULS): A multicentre randomised controlled trial. *Lancet*. 2019; 394(10192):51-62. PMID 31128926
56. Boardsworth K, Rashid U, Olsen S, et al. Upper limb robotic rehabilitation following stroke: A systematic review and meta-analysis investigating efficacy and the influence of

- device features and program parameters. *J Neuroeng Rehabil.* 2025; 22(1):164. PMID 40671078
57. Chen Z, Wang C, Fan W, et al. Robot-assisted arm training versus therapist-mediated training after stroke: A systematic review and meta-analysis. *J Healthc Eng.* 2020;2020:8810867. PMID 33194159
 58. Ferreira F, Chaves MEA, Oliveira VC, et al. Effect of robot-assisted therapy on participation of people with limited upper limb functioning: A systematic review with grade recommendations. *Occup Ther Int.* 2021 Jul 31;2021:6649549. PMID 34393681
 59. Wu J, Cheng H, Zhang J, et al. Robot-assisted therapy for upper extremity motor impairment after stroke: A systematic review and meta-analysis. *Phys Ther.* 2021; 101:1-13. PMID 33454787
 60. Tseng KC, Wang L, Hsieh C, et al. Portable robots for upper-limb rehabilitation after stroke: A systematic review and meta-analysis. *Ann Med.* 2024; 56(1):2337735. PMID 38640459
 61. Everard G, Declerck L, Detrembleur C, et al. New technologies promoting active upper limb rehabilitation after stroke: An overview and network meta-analysis. *Eur J Phys Rehabil Med.* 2022; 58(4):530-548. PMID 35666491
 62. Zhang L, Jia G, Ma J, et al. Short and long-term effects of robot-assisted therapy on upper limb motor function and activity of daily living in patients post-stroke: A meta-analysis of randomized controlled trials. *J Neuroeng Rehabil.* 2022; 19(1):76. PMID 35864524
 63. Cho KH, Song WK. Effects of two different robot-assisted arm training on upper limb motor function and kinematics in chronic stroke survivors: A randomized controlled trial. *Top Stroke Rehabil.* 2021; 28(4):241-250. PMID 32791945
 64. Lee HC, Kuo FL, Lin YN, et al. Effects of robot-assisted rehabilitation on hand function of people with stroke: A randomized, crossover-controlled, assessor-blinded study. *Am J Occup Ther.* 2021;75(1):7501205020p1-7501205020p11. PMID 33399050
 65. Moggio L, de Sire A, Marotta N, et al. Exoskeleton versus end-effector robot-assisted therapy for finger-hand motor recovery in stroke survivors: Systematic review and meta-analysis. *Top Stroke Rehabil.* 2022; 29(8):539-550. PMID 34420498
 66. Park JH. The effects of robot-assisted left-hand training on hemispatial neglect in older patients with chronic stroke: A pilot and randomized controlled trial. *Medicine (Baltimore).* 2021;100(9):e24781. PMID 33655943
 67. Singh N, Saini M, Kumar N, et al. Evidence of neuroplasticity with robotic hand exoskeleton for post-stroke rehabilitation: A randomized controlled trial. *J Neuroeng Rehabil.* 2021; 18(1):76. PMID33957937
 68. Singh H, Unger J, Zariffa J, et al. Robot-assisted upper extremity rehabilitation for cervical spinal cord injuries: A systematic scoping review. *Disabil Rehabil Assist Technol.* 2018; 13(7):704-715. PMID 29334467
 69. Chen YP, Howard AM. Effects of robotic therapy on upper-extremity function in children with cerebral palsy: A systematic review. *Dev Neurorehabil.* 2016; 19(1):64-71. PMID 24724587

70. Park JM, Park HJ, Yoon SY, et al. Effects of robot-assisted therapy for upper limb rehabilitation after stroke: An umbrella review of systematic reviews. *Stroke*. 2025; 56(5). PMID 40115991
71. Verola S, Ugolini A, Pellicciari L, et al. Clinical relevance of the effects of robotic rehabilitation for upper limb recovery after stroke in randomized studies: A systematic review with meta-analysis. *Arch Physiother*. 2025; 15:118-130. PMID 40416935
72. De Iaco L, Veerbeek JM, Ket JCF, et al. Upper limb robots for recovery of motor arm function in patients with stroke: A systematic review and meta-analysis. *Neurology*. 2024; 103(2):e209495. PMID 38870442
73. 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*. 2018 Sep 3;2018(9):CD006876. PMID 30175845
74. Department of Veterans Affairs and Department of Defense. VA/DoD clinical practice guideline for the management of stroke rehabilitation. Version 5.0. (2024) Department of Veterans Affairs website. Available at healthquality.va.gov (accessed July 15, 2026).
75. NICE (National Institute for Health and Care Excellence): Guideline: Stroke rehabilitation in adults. NG236. Published Oct. 18, 2023. Available at nice.org.uk (accessed July 15, 2025).

Centers for Medicare & Medicaid Services

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare & Medicaid Services does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at cms.hhs.gov.

Policy History/Revision

Date	Description of Change
8/18/2026	New medical document. Use of powered exoskeletons, powered upper extremity orthoses, or rehabilitation robots, including but not limited to those used for ambulation in individuals with lower limb disabilities, is considered experimental, investigational and/or unproven for all indications.