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Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities

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Related Policies (if applicable)
None

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.**

Legislative Mandates

EXCEPTION: For Illinois only: Illinois Public Act 103-0458 [Insurance Code 215 ILCS 5/356z.61] (HB3809 Impaired Children) states all group or individual fully insured PPO, HMO, POS plans amended, delivered, issued, or renewed on or after January 1, 2025 shall provide coverage for therapy, diagnostic testing, and equipment necessary to increase quality of life for children who have been clinically or genetically diagnosed with any disease, syndrome, or disorder that includes low tone neuromuscular impairment, neurological impairment, or cognitive impairment.

Coverage

Use of a powered exoskeleton for ambulation in individuals with lower-limb disabilities **is considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

Description

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.

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)

Regulatory Status

In 2014, ReWalk (LIFE*WARD*, 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 Personal 6.0) 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" to 6'2"); 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.

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.

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, 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 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) 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 T5 to L5.

FDA product code: PHL.

Rationale

Medical policies assess the clinical evidence to determine whether the use of a 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, 2 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. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials 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 (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

<u>Clinical Context and Therapy Purpose</u>

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.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals with spinal cord injury, multiple sclerosis, amyotrophic lateral sclerosis, Guillain-Barré syndrome, and spina bifida.

Interventions
The therapy being considered is powered exoskeleton systems that use posture control and are being evaluated for home use:

- The EksoGT robotic exoskeleton (now updated to EksoNR; Ekso Bionics) is available institutionally for rehabilitation. It is undergoing testing for personal use for ambulation in several registered trials.
- The Indego powered exoskeleton (also known as the Vanderbilt exoskeleton; Parker Hannifin) is used for gait training and is now available for home use. It includes functional electrical stimulation and weighs 29 pounds. Indego has been acquired by Ekso Bionics and is currently available as Ekso Indego Therapy for rehabilitation patients and Ekso Indego Personal for those with spinal cord injury.
- ReWalk Personal 6.0 (LIFE*WARD*) consists of an onboard computer, sensor array, and rechargeable batteries that power the exoskeleton, which are contained in a backpack.
- The X1 Mina® Exoskeleton is a joint project of the National Aeronautics and Space Administration (NASA) Johnson Space Center and the Florida Institute for Human and Machine Cognition. It is being developed to provide mobility for both abled and disabled users, for rehabilitation, and exercise. It weighs 26 kg (57 lb).
- Keeogo (B-Temia) exoskeleton is intended for individuals with stroke in rehabilitation settings. It has been studied for personal use in the outpatient setting.

Powered exoskeleton systems that use joystick control and are being evaluated for home use include:

- REX® (REX Bionics) is designed for clinical use in rehabilitation centers and hospitals. REX® P is designed for personal use and does not require use of crutches or a walker for stability, leaving the user hands-free.
- WPAL® (Wearable Power-Assist Locomotor; Fujita Health University) is designed for use with a custom walker.
- HAL (Hybrid Assistive Limb).
- Phoenix® (SuitX).

Comparators
The following practice is currently being used to treat lower-limb disabilities: standard rehabilitation and/or assistive devices without a powered exoskeleton.

Outcomes
The general outcomes of interest are restoration of mobility, increased function, and improved health status and quality of life for wheelchair-bound individuals. Some of the potential secondary health benefits associated with increased mobility include strength and

cardiovascular health, decreased spasticity, improved bladder and bowel function, and psychosocial health.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

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 & 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)	●
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

[1]Trials 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)		
Domains		
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); NCT02658656	U.S.	15	2016-2021	• Veterans or active duty military personnel ≥18 years of age • With traumatic or non-traumatic SCI of 6 months duration • Using a wheelchair for indoor and outdoor mobility	ReWalk Personal 6.0 exoskeleton (in-home use for 4 months) + wheelchair	Wheelchair only

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 >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	Keeogo exoskeleton	No exoskeleton

				without human assistance		

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 Dijsseldonk 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 Dijsseldonk 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.

Summary of Evidence

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.

Practice Guidelines and Position Statements

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.

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			
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 Exoskeleton Assisted Walking Compared to Standard Exercise Training for Persons With Mobility Issues Due to Multiple Sclerosis	24	Oct 2024 (recruiting)

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

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Centers for Medicare and Medicaid Services (CMS)

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 and Medicaid Services (CMS) 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 <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
06/15/2025	Document updated with literature review. Coverage unchanged. Reference 45 added.
11/15/2023	Reviewed. No changes.
07/15/2022	Document updated with literature review. Coverage unchanged. References 4-6, 8, and 10 added; others removed.
07/01/2021	Reviewed. No changes.
06/15/2020	Document updated with literature review. Coverage unchanged. 1 reference removed.
07/01/2019	Reviewed. No changes.
07/01/2018	Document updated with literature review Coverage unchanged. Reference 6-7 added.
07/15/2017	Reviewed. No changes.
07/01/2016	Document updated with literature review. Coverage unchanged.
11/01/2015	New medical document. Use of a powered exoskeleton for ambulation in patients with lower-limb disabilities is considered experimental, investigational and/or unproven.