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MEDICAL POLICY – 1.03.04

Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities

BCBSA Ref. Policy:	1.03.04		
Effective Date:	Jun. 1, 2025	RELATED MEDICAL POLICIES:	
Last Revised:	May 12, 2025	1.04.05	Microprocessor-Controlled Prostheses for the Lower Limb
Replaces:	N/A	8.03.01	Functional Neuromuscular Electrical Stimulation

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

The word exoskeleton means a skeleton that's outside of the body. In healthcare, an exoskeleton is a robotic system that a person wears. It's a frame that a person wears on the lower part of the body, and it has joints that are intended to mimic how the body works when walking. Exoskeletons have a power supply that moves the limbs. For people who don't have the ability to control their legs, the goal of an exoskeleton is to help them stand, walk, and use stairs. There are a few small studies that have been published about exoskeletons. These studies looked at only a small number of people with spinal cord injuries who used these devices within an institution, like a hospital. There are concerns about how safe they are when used outside of a hospital or similar setting. These concerns include the possibility of tripping and falling. More studies are needed to find out if exoskeletons are safe. For these reasons, exoskeletons are considered unproven (investigational).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Device	Investigational
Powered exoskeleton	**Use of a powered exoskeleton for ambulation in individuals with lower-limb disabilities is considered investigational. This includes but is not limited to the following:** • The ReWalk system • Ekso • Indego • All others

Coding

Code	Description
HCPCS	
K1007	Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review

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. These devices have the potential to restore mobility and, thus, might improve functional status, quality of life, and health status for individuals with spinal cord injury, multiple sclerosis, amyotrophic lateral sclerosis, Guillain-Barré syndrome, and spina bifida.

Background

An exoskeleton is an external structure with joints and links that might be regarded as wearable robots designed around the shape and function of the human body. A powered exoskeleton, 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 on-board computer when to take the next step. Individuals using the powered exoskeleton must be able to use their hands and shoulders with forearm crutches or a walker to maintain balance. Instructions for ambulating with ReWalk[1] are to place the crutches ahead of the body, and then bend the elbows slightly, shifting weight toward the front leg, leaning toward the front leg side. The rear leg will lift slightly off of the ground and then begin to move forward. Using the crutches to straighten up will enable the rear leg to continue moving forward. The process is repeated with the other leg.

To move from a seated to standing position or vice versa, the desired movement is selected by the mode selector on the wrist. There is a 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 two seconds, which triggers the safety mechanism to stop walking. Some individuals have become proficient with ReWalk by the third week of training.[2]

Summary of Evidence

For individuals who have lower-limb disabilities who receive a powered exoskeleton, the evidence includes one systematic review, one randomized controlled trial (RCT), one randomized cross-over study and one case series describing community use. The relevant outcomes are functional outcomes, quality of life, and treatment-related mobility. At the present, evaluation of exoskeletons is limited to small studies primarily performed in institutional settings with individuals 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 and 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 individuals with spinal cord injury using in-home powered exoskeleton plus wheelchair versus wheelchair alone, and reported similar results between both groups. In addition, one randomized, open-label cross-over study and a case series in individuals 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 benefit of these devices outside of the institutional setting. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in **Table 1.**

Table 1. Summary of Key Trials

NCT No.	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; SCI: spinal cord injury.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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 six 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 US 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.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In 2014, ReWalk (ReWalk Robotics, previously Argo Medical Technologies) was granted a de novo 510(k) classification (K131798) by the US Food and Drug Administration (FDA) (class II; 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-risk or low-risk profiles and without predicates that would ordinarily require premarket approval as a class III device to be down-classified in an expedited manner and brought to market with a special control as a class II device.

The ReWalk is intended to enable individuals with spinal cord injury at levels T7 to L5 to perform ambulatory functions with supervision of a specially trained companion in accordance with the user assessment and training certification program. The device is also intended to enable individuals with spinal cord injury at levels T4 to T6 to perform ambulatory functions in

rehabilitation institutions in accordance with the user assessment and training certification program. The ReWalk is not intended for sports or stair climbing.

Candidates for the device should have the following characteristics:

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

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

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

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

In 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 stroke patients in rehabilitation settings.

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

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

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History

Date	Comments
10/01/17	New policy approved September 12, 2017, effective January 5, 2018. Add to Durable Medical Equipment section, Orthotic Devices subsection. This service is considered investigational.
05/01/18	Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018; no references added. Policy statement unchanged.
06/01/19	Annual Review, approved May 7, 2019. Policy updated with literature review through January 2019; no references added. Policy statement unchanged.
06/01/20	Annual Review, approved May 5, 2020. Policy updated with literature review through January 2020; no references added. Policy statement unchanged.
10/01/20	Coding update. Added HCPCS code K1007.
06/01/21	Annual Review, approved May 4, 2021. Policy updated with literature review through January 25, 2021; references added. Policy statement unchanged.
06/01/22	Annual Review, approved May 9, 2022. Policy updated with literature review through January 11, 2022; no references added. Policy statement unchanged. Removed HCPCS E1399.
06/01/23	Annual Review, approved May 5, 2023. Policy updated with literature review through January 23, 2023; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
06/01/24	Annual Review, approved May 13, 2024. Policy updated with literature review through January 18, 2024; no references added. Policy statement unchanged.
06/01/25	Annual Review, approved May 12, 2025. Policy updated with literature review through January 22, 2025; reference added. Policy statement unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit

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