

Corporate Medical Policy

Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities

File Name: powered_exoskeleton_for_ambulation_in_patients_with_lower_limb_disabilities
Origination: 3/2015
Last Review: 2/2024

Description of Procedure or Service

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 and a power source that supplies the energy for limb movement. The goal of the powered exoskeleton is to enable people who do not have volitional movement of their lower extremities to bear weight fully while standing, to ambulate over ground, and to ascend and descend stairs. The devices have the potential to restore mobility, increase function, and improve the 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. In addition to individuals with spinal cord injury, the powered exoskeleton might be used by individuals with multiple sclerosis, amyotrophic lateral sclerosis, Guillain-Barré syndrome, and spina bifida.

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. The ReWalk™ includes an array of sensors and proprietary algorithms that analyze body movements, such as 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 walking with the ReWalk™ are to place the crutches ahead of the body, and then bend the elbows slightly, shifting weight towards the front leg, leaning towards 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 then 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 to 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 individuals are able to obtain proficiency with the ReWalk by the third week of training.

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Regulatory Status

In 2014, the U.S. Food and Drug Administration (FDA) approved marketing of the ReWalk™ (ReWalk Robotics, previously Argo Medical Technologies) as 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 (K131798). The device was reviewed through FDA's de novo classification process, which allows novel products with moderate- or low-risk profiles and without predicates which 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). 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 (ASIA C, ASIA D) and T11 to L5 (ASIA A with Zones of Partial Preservation, ASIA B).

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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.

Related Policies

Microprocessor-Controlled Prostheses for the Lower Limb
Neurostimulation, Electrical

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Use of a powered exoskeleton for ambulation in individuals with lower-limb disabilities is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit

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design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

DME, when eligible for coverage, is covered under the Durable Medical Equipment provision of the member benefit.

The DME supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement.

When Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities is covered

Not applicable.

When Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities is not covered

Use of a powered exoskeleton for ambulation in individuals with lower-limb disabilities is considered investigational.

Policy Guidelines

For individuals who have lower-limb disabilities who receive a powered exoskeleton, the evidence includes one randomized control trial (RCT), one randomized cross-over study and one 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 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 and Go test, 6-minute walk test, and 10-meter walk test. One randomized, open-label cross-over 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 should be assessed. Further study is needed to determine the benefits 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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: K1007

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

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Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.04, 12/11/14

Specialty Matched Consultant Advisory Panel 2/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.04, 3/10/16

Hartigan C, Kandilakis C, Dalley S, et al. Mobility Outcomes Following Five Training Sessions with a Powered Exoskeleton. *Top Spinal Cord Inj Rehabil.* Spring 2015;21(2):93-99. PMID 26364278

Specialty Matched Consultant Advisory Panel 2/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.04, 3/9/2017

Specialty Matched Consultant Advisory Panel 2/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.04, 3/8/2018

Specialty Matched Consultant Advisory Panel 2/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.04, 3/14/2019

Specialty Matched Consultant Advisory Panel 2/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.04, 3/12/2020

Specialty Matched Consultant Advisory Panel 2/2021

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.03.04, 3/11/2021

Specialty Matched Consultant Advisory Panel 2/2022

Specialty Matched Consultant Advisory Panel 2/2023

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

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): 147-58. PMID 26230182

Specialty Matched Consultant Advisory Panel 2/2024

Medical Director Review 2/2024

Policy Implementation/Update Information

3/31/15 New Policy. “Use of a powered exoskeleton for ambulation in patients with lower-limb disabilities is considered investigational”. Senior Medical Director review. (sk)

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- 4/1/16 Specialty Matched Consultant Advisory Panel review 2/24/2016. (sk)
- 4/29/16 References added. Description section updated. Policy Guidelines updated. (sk)
- 3/31/17 Specialty Matched Consultant Advisory Panel review 2/22/2017. (sk)
- 5/26/17 Reference added. Policy Guidelines updated. (sk)
- 4/13/18 Specialty Matched Consultant Advisory Panel review 2/28/2018. Reference added. (sk)
- 3/12/19 Specialty Matched Consultant Advisory Panel review 2/20/2019. (sk)
- 5/14/19 Reference added. (sk)
- 3/10/20 Specialty Matched Consultant Advisory Panel review 2/19/2020. (sk)
- 5/26/20 Reference added. Updated Policy Guidelines section. (bb)
- 3/9/21 Specialty Matched Consultant Advisory Panel review 2/17/2021. (sk)
- 12/30/21 Reference added. Description section updated. Policy Guidelines updated. Code K1007 added to Billing/Coding section. (sk)
- 3/8/22 Specialty Matched Consultant Advisory Panel review 2/16/2022. (sk)
- 3/7/23 Regulatory Status updated. Policy Guidelines updated. E1399 removed from Billing/Coding section. Specialty Matched Consultant Advisory Panel review 2/15/2023. (sk)
- 4/1/24 Updated Regulatory Status. References added. Specialty Matched Consultant Advisory Panel review 2/2024. Medical Director review 2/2024. (rp)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.