BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 1.03.04 Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities

Annual Effective Policy Date: July 1, 2026

Original Policy Date: June 2015

Related Policies:

1.04.05 - Microprocessor-Controlled Prostheses for the Lower Limb
8.03.01 - Functional Neuromuscular Electrical Stimulation

Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities

Description

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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 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-Barr syndrome, and spina bifida.

OBJECTIVE

The objective of this evidence review is to determine whether use of a powered exoskeleton improves mobility and net health outcomes for individuals with lower-limb disabilities.

POLICY STATEMENT

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

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POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Screening (other than the preventive services listed in the brochure) is not covered. Please see Section 6 General exclusions.

Benefits are available for specialized diagnostic genetic testing when it is medically necessary to diagnose and/or manage a patient's existing medical condition. Benefits are not provided for genetic panels when some or all of the tests included in the panel are not covered, are experimental or investigational, or are not medically necessary.

FDA 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 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 adults (≥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.

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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; 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, individuals with spinal cord injuries at levels C4 to L5, and individuals with multiple sclerosis.

FDA product code: PHL.

RATIONALE

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 cross-over 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 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 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.

SUPPLEMENTAL INFORMATION

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Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" 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 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2015	New policy	Policy created with literature review; considered not medically necessary.
March 2017	Replace policy	Policy updated with literature review; references 2, 3, 6, and 7 added. Policy statement unchanged.
June 2018	Replace policy	Policy updated with literature review through January 8, 2018; no references added. Policy statement unchanged except "not medically necessary€š corrected to "investigational€š due to FDA 510k status.
June 2019	Replace policy	Policy updated with literature review through January 6, 2019; no references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through January 30, 2020; no references added. Policy statement unchanged.
June 2021	Replace policy	Policy updated with literature review through January 25, 2021; references added. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through January 11, 2022; no references added. Policy statement unchanged.
June 2023	Replace policy	Policy updated with literature review through January 23, 2023; references added. Minor editorial refinements to policy statements; intent unchanged.
June 2024	Replace policy	Policy updated with literature review through January 18, 2024; no references added. Policy statement unchanged.
June 2025	Replace policy	Policy updated with literature review through January 22, 2025; reference added. Policy statement unchanged.
June 2026	Replace policy	Policy updated with literature review through January 13, 2026; no references added. Policy statement unchanged.

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