BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

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

Effective Policy Date: July 1, 2022

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

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 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.

OBJECTIVE

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

POLICY STATEMENT

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

POLICY GUIDELINES

None

BENEFIT APPLICATION

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

FDA REGULATORY STATUS

In 2014, ReWalk™ (ReWalk Robotics, previously Argo Medical Technologies) was granted a de novo 510(k) classification (K131798) by the 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")
- 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; individuals with spinal cord injuries at levels of C7 to T3.

In 2017, 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)

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.

FDA product code: PHL.

RATIONALE

Summary of Evidence

For individuals who have lower-limb disabilities who receive a powered exoskeleton, the evidence includes 1 randomized cross-over study and several case series. 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. 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.

SUPPLEMENTAL INFORMATION

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.[10,] 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.

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.

REFERENCES

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): 147-58. 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): 535-47. PMID 26340538
4. 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

5. van Dijsseldonk 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
6. 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
7. 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): 93-9. PMID 26364278
8. 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
9. 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): 911-21. PMID 23085703
10. 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

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€□ corrected to "investigational€□ 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.