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

**Effective Date:** July 15, 2018

**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

The ReWalk and Indego are powered exoskeletons that provides user-initiated mobility. 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.

### FDA REGULATORY STATUS

In 2014, ReWalk™ (ReWalk Robotics, previously Argo Medical Technologies) 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™ 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"-6'2")
- Weight does not exceed 100 kg (220 lb).

FDA is requiring ReWalk's manufacturer to complete a postmarket clinical study (PS14001) that will consist of a registry to collect data on adverse events related to the use of the ReWalk™ device and prospectively and systematically assess the adequacy of its training program.

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.

Ekso Bionics submitted an application in December 2014 for home use of the Ekso™ GT robotic exoskeleton. The exoskeleton is currently indicated for ambulatory functions in rehabilitation institutions (K143690).

FDA product code: PHL.

## POLICY STATEMENT

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

## BENEFIT APPLICATION

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

## RATIONALE

### Summary of Evidence

For individuals who have lower-limb disabilities who receive a powered exoskeleton, the evidence includes small case series. Relevant outcomes are functional outcomes, quality of life, and treatment-related mobility. At the present, evaluation of exoskeletons is limited to small studies performed in institutional settings with patients who have SCI. These studies have assessed the user's ability to perform, under close supervision, standard tasks such as the Timed Up & Go test, 6MWT, and 10MWT. A 2016 report from the Veterans Administration has suggested that over 60 training sessions may be needed to achieve proficiency with both indoor and outdoor mobility, including door/threshold navigation, stopping, turning, and reaching. There are concerns about users' safety with these devices under regular conditions, including the potential to trip and fall. Further study is needed to determine whether these devices can be successfully used outside of the institutional setting. The evidence is insufficient to determine the effects of the technology on health outcomes.

## SUPPLEMENTAL INFORMATION

### Practice Guidelines and Position Statements

No guidelines or statements were identified.

### U.S. Preventive Services Task Force Recommendations

Not applicable.

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## Medicare National Coverage

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

## REFERENCES


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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):535-547. PMID 26340538
4. U.S. Food and Drug Administration (FDA). Evaluation of automatic class III designation (de novo) for Argo ReWalk™. 2014; https://www.accessdata.fda.gov/cdrh_docs/reviews/den130034.pdf. Accessed February 26, 2018.
5. 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):911-921. PMID 23085703
6. Asselin PK, Avedissian M, Knezevic S, et al. Training persons with spinal cord injury to ambulate using a powered exoskeleton. *J Vis Exp.* Jun 16 2016(112). PMID 27340808
7. 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


## POLICY HISTORY

| Date | Action | Description |
|---|---|---|
| June 2015 | New Policy | Policy created with literature review; considered not medically necessary. |
| March 2017 | Update Policy | Policy updated with literature review; references 2, 3, 6, and 7 added. Policy statement unchanged. |
| June 2018 | Update 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. |