MEDICAL POLICY – 1.03.04
Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities

BCBSA Ref. Policy: 1.03.04
Effective Date: May 1, 2018
Last Revised: April 18, 2018
Replaces: N/A
RELATED MEDICAL POLICIES: None

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

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>HCPCS E1399</td>
<td>Durable medical equipment, miscellaneous</td>
</tr>
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</table>

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Related Information

N/A

Evidence Review

Description

The ReWalk and other similar devices are powered exoskeletons that provide user-initiated mobility. The goal of the powered exoskeleton is to enable people who do not have the ability
to voluntarily move 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 patients 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 evidence review, consists of an exoskeleton-like framework worn by a person that includes a power source supplying energy for limb movement. The goal of the powered exoskeleton is to enable people who do not have voluntary control 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 patients. 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 those with multiple sclerosis, amyotrophic lateral sclerosis, Guillain-Barré syndrome, and spina bifida.

One type of powered lower-limb exoskeleton (eg, 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 (eg, 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. Patients 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 ReWalk¹ 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 2 seconds, which triggers the safety mechanism to stop walking. Some patients have become proficient with ReWalk by the third week of training.²

Powered exoskeleton systems that use posture control and are being evaluated for home use include:

- The Ekso™ GT robotic exoskeleton (Ekso Bionics, Richmond, CA) is available institutionally for rehabilitation. It is undergoing testing for personal use for ambulation in several registered trials.
- The Indego® powered exoskeleton (also known as the Vanderbilt exoskeleton; Parker Hannifin, Macedonia, OH) is used for gait training and is now available for home use. It includes functional electrical stimulation and weighs 26 pounds.
- ReWalk (ReWalk Robotics, Marlborough, MA) consists of an onboard computer, sensor array, and the rechargeable batteries that power the exoskeleton, which are contained in a backpack. The complete ReWalk system weighs about 16 kg (35 lb).
- The X1 Mina Exoskeleton is a joint project of NASA Johnson Space Center and the Florida Institute for Human and Machine Cognition. It is being developed to provide mobility for both abled and disabled users, for rehabilitation, and exercise. It weighs 26 kg (57 lb).

Powered exoskeleton systems that use joystick control and are being evaluated for home use include:

- REX® (REX Bionics, Auckland, New Zealand) is designed for rehabilitation centers and hospitals. REX® P is designed for personal use and does not require use of crutches or a walker for stability, leaving the user hands-free.
- WPAL (Wearable Power-Assist Locomotor; Fugita Health University, Japan) is designed for use with a custom walker.
- HAL (Hybrid Assistive Limb)
- Phoenix (suitX)

**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 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 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 the safety of these devices under regular use, 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.

Ongoing and Unpublished Clinical Trials

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

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
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<tr>
<td>NCT01701388</td>
<td>Investigational Study of the Ekso Powered Exoskeleton for Ambulation in Individuals With Spinal Cord Injury (or Similar Neurological Weakness)</td>
<td>40</td>
<td>Apr 2017</td>
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<tr>
<td>NCT03082898</td>
<td>Mobility and Therapeutic Benefits Resulting From Exoskeleton Use in a Clinical Setting (SC140121 Study 1)</td>
<td>24</td>
<td>Jun 2020</td>
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<tr>
<td>NCT02658656</td>
<td>Exoskeleton Assisted-Walking in Persons With SCI: Impact on Quality of Life</td>
<td>160</td>
<td>Aug 2020</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
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NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.
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.

Regulatory Status

In 2014, ReWalk™ (ReWalk Robotics, previously Argo Medical Technologies) was granted a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA) (class II; product code: PHL; K131798). 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)
The 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). 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 (Richmond, CA) 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.

References

### Date | Comments
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10/01/17 | New policy approved September 12, 2017, effective January 5, 2018. Add to Durable Medical Equipment section. 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.

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200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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