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

<table>
<thead>
<tr>
<th>Device</th>
<th>Investigational</th>
</tr>
</thead>
</table>
| **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>
</tr>
</thead>
<tbody>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
</tr>
<tr>
<td>K1007</td>
<td>Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors (New code effective 10/1/20)</td>
</tr>
</tbody>
</table>

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Related Information

N/A

Evidence Review
Description

The ReWalk and Indego are powered exoskeletons that provide 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. 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.

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 ambulating 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 two seconds, which triggers the safety mechanism to stop walking. Some patients have become proficient with ReWalk by the third week of training.²
Summary of Evidence

For individuals who have lower-limb disabilities who receive a powered exoskeleton, the evidence includes case series. The 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 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.

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>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
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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>Sep 2020</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>Dec 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>Sep 2021</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02202538*</td>
<td>Indego® Exoskeleton; Assessing Mobility for Persons With Spinal Cord Injury (SCI).</td>
<td>45</td>
<td>Oct 2015 (completed)</td>
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</tbody>
</table>
Medicare National Coverage

There is no national coverage determination.

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; 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-risk 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.

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).

FDA product code: PHL.

References


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/01/17</td>
<td>New policy approved September 12, 2017, effective January 5, 2018. Add to Durable Medical Equipment section, Orthotic Devices subsection. This service is considered investigational.</td>
</tr>
<tr>
<td>05/01/18</td>
<td>Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018; no references added. Policy statement unchanged.</td>
</tr>
<tr>
<td>10/01/20</td>
<td>Coding update. Added HCPCS code K1007.</td>
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  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  - Information written in other languages

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PO Box 91102, Seattle, WA 98111
Toll free 855-332-6396, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@LifeWiseHealth.com

You can file a grievance in person by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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阿拉伯语

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