Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities

Policy Number: 1.03.04  Last Review: 3/2017
Origination: 3/2015  Next Review: 3/2018

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage Powered Exoskeleton for Ambulation in Patients with Lower-Limb Disabilities. This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
Use of a powered exoskeleton for ambulation in patients with lower-limb disabilities is considered investigational.

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
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<td>With lower-limb disabilities</td>
<td>• Powered exoskeleton</td>
<td>• Wheelchair</td>
<td>• Functional outcomes</td>
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<td></td>
<td></td>
<td></td>
<td>• Quality of life</td>
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<td>• Treatment-related morbidity</td>
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The ReWalk™ is a powered exoskeleton 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, may lead to improvements in 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.

The evidence for the powered exoskeleton in individuals who have lower-limb disabilities includes small case series. Relevant outcomes are functional outcomes, quality of life, and treatment-related mobility. At the present, evaluation of the
ReWalk exoskeleton is limited to small studies performed in the laboratory setting. 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. An occasional loss of balance has been noted, raising concerns about the safety of the device under regular use. Further study is needed to determine whether this device can be successfully used outside of the investigational (laboratory) setting. A study of 16 patients who were trained with the Indego powered exoskeleton reported that 6 of 8 patients were able to walk unassisted and 6 of the 8 patients were able to walk on both indoor and outdoor surfaces including ramps, sidewalks, and grass. Further study for longer periods is needed. In addition, this device is not cleared for marketing in the United States. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Background**

An exoskeleton is an external structure with joints and links that correspond to parts of the human body. A powered exoskeleton, as described in this policy, consists of an exoskeleton-like framework worn by a person and a power source that supplies the energy for limb movement. Exoskeletons might be regarded as wearable robots designed around the shape and function of the human body. The goal of the powered exoskeleton is to enable people who do not have volitional movement 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 patients with multiple sclerosis, amyotrophic lateral sclerosis, Guillain-Barré syndrome, and spina bifida.

The ReWalk Personal System (ReWalk Robotics) is a powered lower-limb exoskeleton that provides user-initiated mobility based on postural information and selection of standing, walking, sitting, and stair up/down modes via a mode selector on a wristband. The ReWalk includes an array of sensors and proprietary algorithms that analyze body movements, such as 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 the ReWalk(1) are to place the crutches ahead of the body. Then bend the elbows slightly, shifting weight towards the front leg, leaning towards 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 then 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 to 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 are able to obtain proficiency with the ReWalk by the third week of training.(2)

The onboard computer, sensor array, and the rechargeable batteries that power the exoskeleton are contained in a backpack. The complete ReWalk system weighs about 35 pounds.

Other powered exoskeleton systems that are in development or are currently used in the rehabilitation setting are:

- The Indego® powered exoskeleton (also known as the Vanderbilt exoskeleton; Parker Hannifin, Macedonia, OH) is used for gait training and is being evaluated for home use. It weighs 26 pounds and is currently available for use in Europe.
- 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 57 pounds.
- The Ekso™ GT robotic exoskeleton (Ekso Bionics, Richmond, CA) is available for institutional use for rehabilitation. It is undergoing testing for personal use for ambulation in several registered trials.
- REX® (REX Bionics, Auckland, New Zealand) is designed for rehabilitation centers and hospitals. REX P is designed for personal use and is controlled by a joystick.

REGULATORY STATUS
In 2014, ReWalk™ (ReWalk Bionics, 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. The ReWalk™ device 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 processs 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 Argo Medical Technologies 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.

Ekso Bionics (Richmond, CA) submitted a 510K application in December 2014 for the Ekso™ GT robotic exoskeleton.

**Rationale**

This evidence review was created in December 2014 and updated periodically using the MEDLINE database. The most recent literature update was performed through January 26, 2016.

Although the optimal study design for a therapeutic intervention is a randomized controlled trial, it is recognized that controlled trials in this population are unlikely to be performed. Studies that use a pre-post design may contribute to an understanding of the effects of a powered exoskeleton on health outcomes. Outcomes of interest are the safety of the device, the effect of the exoskeleton on the ability to ambulate, and the downstream effect of ambulation on other health outcomes, such as bowel and bladder function, spasticity, and cardiovascular health. Of importance in this severely disabled population is the impact of this technology on activities of daily living, which can promote independence and improved quality of life.

Issues that need to be addressed include the device’s performance over the longer term when walking compared to wheelchair mobility, the user’s usual locomotion outside of the laboratory setting, and the use of different exoskeletons or the training context in which one is used.(3)

**ReWalk**

Several small series have been identified for the ReWalk. A study included in the application to the U.S. Food and Drug Administration was a multicenter evaluation
of performance with the ReWalk in 24 individuals with spinal cord injury.(4) Screening criteria included complete motor cervical (C7-C8) or thoracic (T1-T12) spinal cord injury; age between 18 and 55 years; regular use of a reciprocating gait orthosis, knee ankle foot orthosis, or standing device; height between 160 to 190 cm, and weight less than 100 kg. Study participants received 16 to 24 training sessions of 60 to 90 minutes duration over the course of about 8 weeks. The primary outcome measures were the 10-meter walk test (10MWT) and the 6-minute walk test (6MWT). Results for the 6MWT were available for 20 participants, who walked for a range of 0 to over 100 meters in 6 minutes. For the 10MWT, 22 of the 24 participants required between 10 to more than 100 seconds to walk 10 meters.

In 2012, Esquenazi et al published a safety and efficacy trial of the ReWalk in 12 subjects with motor-complete thoracic spinal cord injury.(5) All had lower-limb bone and joint integrity, adequate joint range of motion, and a history of standing (either with lower-limb bracing or a standing frame) on a frequent basis. Over the course of 8 weeks, subjects received up to 24 sessions of training lasting 60 to 90 minutes per session that included stepping, sit-to-stand, standing, and stand-to-sit transfers. During this time, the unsupervised use of the exoskeleton was not allowed. All 12 participants completed training and were able to independently transfer and walk for at least 50 to 100 meters for a period of at least 5 to 10 minutes. Participants did occasionally lose their balance and either caught themselves with their crutches or were stabilized by the physical therapist. With monitoring of walking, there were no serious adverse events such as falls, bone fractures, or episodes of autonomic dysreflexia. Self-reported health benefits collected at the end of training from 11 subjects included improved spasticity (n=3) and bowel regulation (n=5).

A 2012 report by Zeilig et al describes a pilot study of the ReWalk in 6 patients with spinal cord injuries.(1) Study participants required an average of 13.7 training sessions (SD=5.8), each lasting an average of 50 minutes, before they were able to complete the Timed Up and Go test, 10MWT, and 6MWT. The average distance walked in 6 minutes was 47 meters (SD=20.8), and was highly correlated with the level of the spinal cord injury. There were no falls or skin or joint injuries during testing, and following training, subjects reported that they felt safe and comfortable using the device. Blood pressure and pulse rate were within the range consistent with physical activity.

**Indego**

A key question is whether a powered exoskeleton can be used independently and safely outside of the investigational setting. The Indego powered exoskeleton was evaluated after 5 training sessions (lasting 1.5 hours each for 5 consecutive days) in 16 patients with spinal cord injury between C5 and L1.(6) Testing included the 6MWT and 10MWT. Following training, 3 patients with motor complete tetraplegia (C5-C7 injury level) were able to ambulate on indoor surfaces (hard flooring, carpet, and thresholds), outdoor surfaces (sidewalks), elevators, and ramps in compliance with the Americans with Disabilities Act, using a walker with assistance from 1 or 2 therapists. In the group of 5 patients with upper paraplegia (T1-T8
injury level) 2 walked with supervision and 3 required only minimal assistance from a therapist. All of the patients in this group were able to walk on indoor surfaces, outdoor surfaces, and in elevators; 4 of 5 were successfully tested on ramps. Among the 8 patients with lower paraplegia (T9-L1 injury level) who were evaluated, 4 used a rolling walker and 4 used forearm crutches. After training for 5 days, 6 of the 8 were able to walk without assistance and 2 required minimal assistance from a therapist. Six were able to ambulate on indoor surfaces, outdoor surfaces, elevators, ramps, and grass. No studies were identified that evaluated the Indego for durations longer than the 10MWT, and the device is not yet cleared for marketing in the United States.

**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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<tbody>
<tr>
<td>NCT02132702a</td>
<td>Performance Attributes and User Progression While Using Ekso Robotic Exoskeleton in an Eight Week, Over Ground, Locomotor Program in Individuals With Spinal Cord Injury</td>
<td>65</td>
<td>Jan 2017</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>Apr 2017</td>
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<tr>
<td>NCT02118194</td>
<td>Assessment of Home/Work Simulation Tasks and Community Mobility Skills in the ReWalk Powered Exoskeleton in Persons With Spinal Cord Injury</td>
<td>40</td>
<td>Sep 2017</td>
</tr>
<tr>
<td>NCT02104622</td>
<td>Identify Training Strategies for Progressing Exoskeleton Users Towards Everyday Functional Ambulation</td>
<td>40</td>
<td>Sep 2017</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

### Summary of Evidence
The evidence for the powered exoskeleton in individuals who have lower-limb disabilities includes small case series. Relevant outcomes are functional outcomes, quality of life, and treatment-related mobility. At the present, evaluation of the ReWalk exoskeleton is limited to small studies performed in the laboratory setting. 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. An occasional loss of balance has been noted, raising concerns about the safety of the device under regular use. Further study is needed to
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SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements
No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations
Not applicable.

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:

Billing Coding/Physician Documentation Information
E1399 Durable medical equipment, miscellaneous

ICD-10 Codes
G12.21 Amyotrophic lateral sclerosis
G35 Multiple sclerosis
G61.0 Guillain-Barre syndrome
Q05.0- Spina bifida code range
Q05.9
S34.101- Injury of lumbar and sacral spinal cord and nerves at abdomen, lower
S34.139  back and pelvis level code range

There is no specific code for these devices. An unlisted HCPCS code such as E1399 would likely be reported.

Additional Policy Key Words
N/A

Policy Implementation/Update Information
3/1/16  No policy statement changes.
3/1/17  No policy statement changes.

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