Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities

Summary

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-Barre syndrome and spina bifida.

At the present time, evaluation of the powered exoskeleton outside of the rehabilitation setting 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 (TUG), 6 min walk test (6MWT) and 10 meter walk test (10MWT). 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 these devices can be used successfully outside of the investigational setting and whether their use leads to an improvement in health and quality of life for this severely disabled population.

Related Policies
1.04.05 Microprocessor-Controlled Prostheses for the Lower Limb
8.03.01 Functional Neuromuscular Electrical Stimulation

Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Use of a powered exoskeleton for ambulation in patients with lower limb disabilities is considered not medically necessary.

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-Barre syndrome and Spina Bifida.

The ReWalk™ Personal System (ARGO Medical Technologies, Israel) 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 remote control 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™ are as follows: 1) Set the crutches ahead of the body and shift the body’s mass towards the forward, front leg. 2) With the crutches on the ground, bend the elbows and continue “falling”, leaning more towards the front leg side. The rear leg will be lifted slightly off of the ground. Then the rear leg will begin to move forward. 3) Push the crutches to straighten up thereby enabling the rear leg to continue moving forward. 4) As the rear leg completes its motion, prepare to repeat the process.

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

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

- The Ekso™ GT robotic exoskeleton (Ekso Bionics, Richmond, CA) is a Class I medical device that is available for institutional use. It is undergoing testing in several registered trials.
- Rex® Rehab™ (Rex Bionics, Auckland, New Zealand) is designed for rehabilitation centers and hospitals. Rex Personal™ is designed for personal use and is controlled by a joystick.

**Regulatory Status**

In 2014, the U.S. Food and Drug Administration (FDA) approved marketing of the ReWalk™ as 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 (K131798). The device was reviewed through FDA’s de novo classification process which allows novel products with moderate or low risk profiles and without predicates which 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. FDA product code: PHL
The Argo 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 lbs)

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.

Rationale

This policy was created with a search of the MEDLINE database through November 11, 2014. 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 utilize 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.

Several small series have been identified for the ReWalk™. A study included in the FDA application was a multicenter evaluation of performance with the ReWalk™ in 24 individuals with spinal cord injury.\(^2\) 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. The participants received 16 – 24 training sessions of 60-90 minutes over the course of about 8 weeks. The primary outcome measures were the 10 meter walk test (10MWT) and the 6 min walk test (6MWT). Results for the 6MWT were available for 20 participants, who walked for a range of 0 meters to over 100 meters in 6 minutes. Twenty-two of the 24 participants required between 10 and more than 100 seconds to walk 10 meters.
In 2012, Esquenazi et al published a safety and efficacy trial of the ReWalk in 12 participants with motor-complete thoracic spinal cord injury. The patients in this report had lower limb bone and joint integrity, adequate range of joint motion, and a history of standing (either with lower limb bracing or a standing frame) on a frequent basis. The participants had training that included stepping, sit-to-stand, standing, and stand-to-sit transfers in up to 24 sessions of 60- to 90-min over a period of 8 weeks. The participants were not allowed to use the device unsupervised. All 12 participants who completed training in this study were able to independently transfer and walk for at least 50 to 100 m for a period of at least 5 to 10 min. 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 dysregulation. Self-reported health benefits at the end of training 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. The participants required an average of 13.7 training sessions to be able to complete the Timed Up and Go (TUG) test, timed 10-m walk, and distance walked in 6 minutes. The average distance walked in 6 minutes was 47 m, and was highly correlated with the level of the spinal cord injury. There were no falls or skin or joint injuries. Blood pressure and pulse rate were within normal range for physical activity. The subjects reported that they felt safe and comfortable with the device.

**Ongoing and Unpublished Clinical Trials**

An online search of the site ClinicalTrials.gov in November 2014 found a number of trials on the ReWalk™ and Ekso™ systems, including the following:

**Home/Work, Community Mobility Skills in the ReWalk Exoskeleton in Persons With SCI (VA_ReWalk2) NCT02118194** The overall goal of this project is to determine if non-ambulatory persons with spinal cord injury who have already participated in at least 20 sessions of ReWalk training can be further trained to achieve more advanced skills for use in the home or work place environments and outdoor community mobility skills. The walking tests (10mWT, 6-minWT, TUG) will be performed indoors on tile/linoleum and carpet and outdoors on concrete, asphalt, grass, dirt, uneven surfaces, curbs, curb cutouts, and ramps. The advanced indoor standing skills include counter top work, retrieving of items from an overhead cabinet and from a refrigerator. The door navigation skills include a push button door, elevator doors, revolving doors, and non-powered doors. The study has an estimated enrollment of 40 participants. Study completion is expected September 2017.

**Identify Training Strategies for Progressing Exoskeleton Users Towards Everyday Functional Ambulation (NCT02104622)** This is a Phase II study sponsored by the Rehabilitation Institute of Chicago that will examine the potential of the ReWalk™ for everyday use, including ramps, stairs, curbs and indoor and outdoor use. The primary outcome measures include measurements of gait over ground and ability to negotiate stairs, ramps, curbs, and turning and distance able to reach while standing and sitting. Secondary outcome measures include patient perception of Quality of Life, the Psychosocial Impact of Assistive Devices Scale, Activities-specific Balance Confidence Scale, Self-reported Spinal Cord Independence Measure in activities of daily living, and pain measured with a...
visual analog scale. The study has a targeted enrollment of 20 participants with completion expected September 2017.

**EKSO Trial: Powered Exoskeleton for Ambulation in Subjects With SCI (Spinal Cord Injury, NCT01701388)** This is a Phase I study sponsored by the Rehabilitation Institute of Chicago. This study seeks to test the safety and efficacy of the Ekso™ device in spinal cord injury population and in populations with similar neurological weakness to the SCI population. The study is currently recruiting patients with spinal cord injury or similar neurological weakness and has a target enrollment of 40 participants. Study completion is expected in April 2017.

**Safety Study of Outdoor and Indoor Mobility in People With Spinal Cord Injury (ROBOtics Spinal Cord Injury EKSO). (ROBOSCIEKSO, NCT02065830)** The aim of this study will be to evaluate the safety and the efficacy of the Ekso™ device in subjects with spinal cord injury and in subjects with other neurological disease with an impairment of lower limbs. The study has an estimated enrollment of 30 participants; recruitment had not started as of July 2014. Study completion is expected in March 2016.

**Performance Attributes and User Progression While Using EKSO (NCT02132702)** This industry-sponsored study will evaluate the performance attributes and user progression of participants with motor complete and incomplete spinal cord injury (SCI) while utilizing the Ekso™ robotic exoskeleton in an eight week over ground, locomotor program. Secondary outcome measures will assess the cardiovascular effect, spasticity, strength, bladder and bowel function, functional abilities, gait, balance, and quality of life. This study is not yet open for recruitment. Completion is expected January 2017.

### Summary of Evidence

At the present time, evaluation of the powered exoskeleton outside of the rehabilitation setting 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 (TUG), 6 min walk test (6MWT) and 10 m walk test (10MWT). 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 these devices can be used successfully outside of the investigational setting and whether their use leads to an improvement in health and quality of life for this severely disabled population.

### Supplemental Information

#### Practice Guidelines and Position Statements

No guidelines or position statements were identified.

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

Not applicable.
Medicare National Coverage

There is no national coverage determination (NCD).

References


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<th>Policy History</th>
<th>Date</th>
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<tbody>
<tr>
<td></td>
<td>June 2015</td>
<td>New Policy</td>
<td>Policy created with literature review; considered not medically necessary.</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 19, 2015 and is effective July 15, 2015.

*Signature on file*

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