Corporate Medical Policy

Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities

Description of Procedure or Service

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 (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 toward 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 pounds.

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 available for
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institutional use for rehabilitation. It is undergoing testing for personal use for ambulation 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, 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.

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 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 submitted a 510K application December 2014 for the Ekso™ GT robotic exoskeleton.

Related Policies

Microprocessor-Controlled Prostheses for the Lower Limb Neurostimulation, Electrical

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

Use of a powered exoskeleton for ambulation in patients with lower-limb disabilities is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application
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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy. DME, when eligible for coverage, is covered under the Durable Medical Equipment provision of the member benefit.

The DME supplier must meet eligibility and/or credentialing requirements as defined by the Plan to be eligible for reimbursement.

When Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities is covered

Not applicable.

When Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities is not covered

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

Policy Guidelines

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 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 these devices can be successfully used outside of the investigational (laboratory) setting.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

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

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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**Policy Implementation/Update Information**

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<td>3/31/15</td>
<td>New Policy</td>
<td>“Use of a powered exoskeleton for ambulation in patients with lower-limb disabilities is considered investigational”. Senior Medical Director review. (sk)</td>
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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.