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 policy, consists of an exoskeleton-like framework worn by a person and a power source that supplies the energy for limb movement. 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™ 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.

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.
Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities

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

- 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.
- 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 able 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.

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.

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.

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 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.
Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities

In 2016, Indego® (Parker Hannifin) was cleared for marketing by FDA through the 510(k) process (K152416). 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 submitted a 510K application December 2014 for the Ekso™ GT robotic exoskeleton. The exoskeleton is currently indicated for ambulatory functions in rehabilitation institutions (K143690).

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**

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**

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
Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities

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.

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 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


Specialty Matched Consultant Advisory Panel 2/2017


Policy Implementation/Update Information

3/31/15 New Policy. “Use of a powered exoskeleton for ambulation in patients with lower-limb disabilities is considered investigational”. Senior Medical Director review. (sk)

4/1/16 Specialty Matched Consultant Advisory Panel review 2/24/2016. (sk)

4/29/16 References added. Description section updated. Policy Guidelines updated. (sk)


5/26/17 Reference added. Policy Guidelines updated. (sk)
Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities

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.