Policy Statement

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

Policy Guidelines

There is no specific code for powered exoskeleton devices. The following unlisted HCPCS code would likely be reported:
- E1399: Durable medical equipment, miscellaneous

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. The 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-Barre syndrome, and spina bifida.

Related Policies

- Functional Neuromuscular Electrical Stimulation
- Microprocessor-Controlled Prostheses for the Lower Limb

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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; FDA 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- 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 lbs).

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 the 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

Rationale

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 (e.g., 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 (e.g., tilt of the torso) and manipulate the motorized leg braces. The tilt sensor is used to signal the onboard 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

**Literature Review**

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Pre-post study designs (patient as their own control) are most likely to provide evidence on 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 (e.g., bowel and bladder function, spas ticity, 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 QOL.

Issues that need to be assessed include the device’s performance over the longer-term when walking compared with wheelchair mobility, the user’s usual locomotion outside of the laboratory setting, and the use of different exoskeletons or the training context.3 Adverse events (e.g., falling, tripping) can impact both safety and psychological security and also need to be assessed.
Powered Exoskeleton for Ambulation

Clinical Context and Therapy Purpose
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 powersource supplying 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 question addressed in this evidence review is does use of powered exoskeleton improve the mobility and health outcomes for individuals with lower-limb disabilities?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest are patients with spinal cord injury. In addition to individuals with spinal cord injury, the powered exoskeleton might be used by those with multiple sclerosis, amyotrophic lateral sclerosis, Guillain-Barré syndrome, and spina bifida.

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

- The Ekso™ GT robotic exoskeleton (Ekso Bionics) is available institutionally for rehabilitation. It is undergoing testing for personal use for ambulation in several registered trials.
- The Indego® powered exoskeleton (also known as the Vanderbilt exoskeleton; Parker Hannifin) is used for gait training and is now available for home use. It includes functional electrical stimulation and weighs 26 pounds.
- ReWalk (ReWalk Robotics) consists of an onboard computer, sensor array, and the rechargeable batteries that power the exoskeleton, which are contained in a backpack. The complete ReWalk system weighs about 16 kg (35 lbs.).
- 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 26 kg (57 lbs.).

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

- REX® (REX Bionics) 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) is designed for use with a custom walker
- HAL (Hybrid Assistive Limb)
- Phoenix (suitX).

Comparator
Standard rehabilitation without a powered exoskeleton.

Outcomes
The devices have the potential to restore mobility, increase function, and improve the health status and QOL 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.

ReWalk
There is limited information about the use of ReWalk outside of the institutional setting. Several small series have been identified for ReWalk in an institutional setting. Standard measures of
walking function include the Timed Up & Go test, which assesses the time required to get up from a chair and commence walking, the 10-meter walk test (10MWT), which evaluates the time required to walk ten meters, and the 6-minute walk test (6MWT), which measures the distance walked in six minutes.

Included in the device 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 (SCI). Screening criteria included complete motor cervical (C7-C8) or thoracic (T1-T12) SCI; 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 in duration over about 8 weeks. The primary outcome measures were distance on the 10MWT and the 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.

Esquenazi et al (2012) published a safety and efficacy trial of the ReWalk in 12 subjects with motor complete thoracic SCI. 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 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, 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 reduced spasticity (n=3) and improved bowel regulation (n=5).

A report by Zeilig et al (2012) described a pilot study of ReWalk in 6 patients with SCI. Study participants required an average of 13.7 training sessions, each lasting an average of 50 minutes, before they were able to complete the Timed Up & Go, 10MWT, and 6MWT. The average distance walked in 6 minutes was 47 meters, which correlated highly with the level of the SCI. 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 rates were within the range consistent with physical activity.

Asselin et al (2016) from the Department of Veterans Affairs reported on screening criteria, fitting, and training procedures for use of a powered exoskeleton. Skills practiced included standing, sitting, standing balance, progression with both indoor and outdoor walking, and tasks that included reaching, stopping, turning, and door/threshold navigation. Training sessions were conducted for 60 to 90 minutes, 3 times a week, with at least 60 training sessions per patient.

**Indego**

As noted, 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 SCI between C5 and L1. Testing included the 6MWT and 10MWT. Following training, 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, using a walker with assistance from one or two therapists. In the group of patients with upper paraplegia (T1-T8 injury level), all were able to walk on indoor surfaces, outdoor surfaces, and in elevators; and most were successfully tested on ramps. Among the eight patients with lower paraplegia (T9-L1 injury level), six were able to walk without assistance on indoor surfaces, outdoor surfaces, elevators, ramps, and grass, and two required minimal assistance from a therapist. No studies were identified that evaluated the Indego for distances beyond ten meters.
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, QOL, and treatment-related mobility. At the present, evaluation of exoskeletons is limited to small studies performed in institutional settings with patients who have SCI. These studies have assessed the user’s ability to perform, under close supervision, standard tasks such as the Timed Up & Go test, 6MWT, and 10MWT. 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.

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. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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>
<td></td>
</tr>
<tr>
<td>NC01701388</td>
<td>Investigational Study of the Ekso Powered Exoskeleton for Ambulation in</td>
<td>40</td>
<td>Jun 2019</td>
</tr>
<tr>
<td></td>
<td>Individuals With Spinal Cord Injury (or Similar Neurological Weakness)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NC03082898</td>
<td>Mobility and Therapeutic Benefits Resulting From Exoskeleton Use in a</td>
<td>24</td>
<td>Jun 2020</td>
</tr>
<tr>
<td></td>
<td>Clinical Setting (SC140121 Study 1)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NC02658656</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>NC02202538a</td>
<td>Indego® Exoskeleton; Assessing Mobility for Persons With Spinal Cord Injury (SCI)</td>
<td>45</td>
<td>Oct 2015 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

References

3. Lajeunesse V, Vincent C, Routhier F, et al. Exoskeletons' design and usefulness evidence according to a systematic review of lower limb exoskeletons used for functional mobility
1.03.04  Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities


Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

IE

The following services may be considered investigational.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>HCPCS</td>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
</tr>
<tr>
<td>ICD-10 Procedure</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/01/2016</td>
<td>BCBSA Medical Policy Adoption</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>05/01/2017</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>05/01/2018</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>05/01/2019</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
</tbody>
</table>

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not
investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.