Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities

Policy #: 575
Latest Review Date: March 2023
Category: DME
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage*

Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).

POLICY:

Blue Advantage will treat **use of a powered exoskeleton for ambulation in patients with lower limb disabilities** as a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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 evidence review, consists of an exoskeleton-like framework worn by a person and a power source that supplies the 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 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 seated to standing or from standing to seated, 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 sec, which triggers a safety mechanism to stop walking. Some patients are able to obtain proficiency with the ReWalk by the third week of training.

KEY POINTS:

The most recent literature review was updated through January 23, 2023.

Summary of Evidence:

For individuals who have lower-limb disabilities who receive a powered exoskeleton, the evidence includes 1 systematic review, 1 randomized control trial (RCT), 1 randomized cross-over study, and 1 case series describing community use. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. At the present, evaluation of exoskeletons is limited to small studies primarily 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 as the Timed Up & Go test, 6-minutewalk test, and 10-meter walk test. A recent systematic review included these studies and qualitatively described the effects of powered exoskeletons on walking and on secondary health conditions. However, lack of high-quality studies and heterogeneity of outcome measures precluded the ability to make general conclusions. Evidence on the use of powered exoskeletons in the community or home setting is even more limited. A recent RCT compared quality of life measures in patients with spinal cord injury using in-home powered exoskeleton plus wheelchair versus wheelchair alone, and reported similar results between both groups. In addition, 1 randomized, open-label cross-over study and a case series in patients with multiple sclerosis and spinal cord injury, respectively, assessed use of powered exoskeletons in the outpatient setting. Although these studies indicate powered exoskeletons may be used safely in the outpatient setting, these devices require significant training, and their efficacy has been minimally evaluated. Further evaluation of users' safety with these devices under regular conditions, including the potential to trip and fall, is necessary. Additional studies, particularly high-quality RCTs, are needed to determine the benefits of these devices both inside and outside of the institutional setting. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements:

American Physical Therapy Association

The American Physical Therapy Association published guidelines in 2020 providing recommendations to guide improvement of locomotor function after brain injury, stroke, or incomplete spinal cord injury in ambulatory patients. The guidelines recommend against the use of powered exoskeletons for use on a treadmill or elliptical to improve walking speed or distance following acute-onset central nervous system injury in patients more than 6 months post-injury due to minimal benefit and increased costs and time.

A 2022 article by Hohl et al comments on how this guideline recommendation adds uncertainty to the clinical application of powered exoskeletons in rehabilitation. Several studies referenced in the guideline did not use the Food and Drug Administration (FDA)-approved devices discussed in this review; rather, the guideline focused on treadmill-based robots, specifically the

Lokomat®. Therefore, the conclusions should be interpreted with caution, given the substantial differences in functionality and physical demand between the treadmill-based robots and the powered exoskeletons of interest. Taking into consideration the limited guidance on proper use of powered exoskeletons, Hohl et al developed a framework for clinical utilization of powered exoskeletons in rehabilitation settings. The aims of the framework are to: 1) assist practitioners with clinical decision making of when exoskeleton use is clinically indicated, 2) help identify which device is most appropriate based on patient deficits and device characteristics, 3) provide guidance on dosage parameters within a plan of care, and 4) provide guidance for reflection following utilization. The framework focuses specifically on clinical application, not use of powered exoskeletons for personal mobility.

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

KEY WORDS:

ReWalk, Ekso GT Robotic Exoskeleton, Rex Rehab, Argo Rewalk, Indego® Powered Exoskeleton, Vanderbilt Exoskeleton, Mina X-1, Power Assist Exoskeleton, REX®, REX P®, Rewalk, WPAL (Wearable Power-Assist Locomotor), X1 Mina, HAL (Hybrid Assistive Limb), Phoenix, Keeogo, ReWalk ReStore, ExoAtlet-II, Ekso, Ekso GT, GEMS-H, EksoNR, Atalante, Lokomat®.

APPROVED BY GOVERNING BODIES:

In 2014, ReWalk™ (ReWalk Robotics, previously Argo Medical Technologies) was granted a de novo 510(k) classification by the U.S. Food and Drug Administration (FDA) (class II). 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 process 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 T7to 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"), and
- Weight does not exceed 100 kg (220 lbs).

In 2019, the ReWalk ReStore™, a lightweight, wearable, exo-suit, was approved for rehabilitation of individuals with lower- limb disabilities due to stroke.

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 the ReWalk™ as a predicate device. The 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, and individuals with spinal cord injuries at levels of C7 to T3.

In 2017, Hybrid Assistive Limb (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 (American Spinal Injury Association [ASIA] Impairment Scale C, ASIA D) and T11 to L5 (ASIA A with Zones of Partial Preservation, ASIA B)

In 2020, Keeogo™ (B-Temia) exoskeleton was cleared for marketing by the FDA through the 510(k) process (K201539). The Honda Walking Assist Device was the predicate device.Keeogo is intended for use in patients with stroke in rehabilitation settings.

In 2021, ExoAtlet-II® (ExoAtlet Asia Co. Ltd.) was cleared for marketing by the FDA through the 510(k) process (K201473). The Ekso/Ekso GT was the predicate device. ExoAtlet-II 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 spinal cord injuries at levels T4 to L5, and individuals with spinal cord injuries at levels of C7 to T3 (ASIA D)

In 2022, GEMS-H® (Samsung Electronics Co. Ltd.) was cleared for marketing by the FDA through the 510(k) process (K213452). The Honda Walking Assist Device was the predicate device. GEMS-H is intended to help assist ambulatory function in rehabilitation institutions under the supervision of a trained healthcare professional for individuals with stroke who have gait deficits and exhibit gait speeds of at least 0.4 m/s and are able to walk at least 10 meters with assistance from a maximum of 1 person.

In 2022, EksoNR™ (Ekso Bionics Inc) was cleared for marketing by the FDA through the 510(k) process (K220988). EksoNR is intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for the following populations: individuals with multiple sclerosis (upper extremity motor function of at least 4/5 in at least 1 arm); individuals with acquired brain injury, including traumatic brain injury and stroke (upper extremity motor function of at least 4/5 in at least 1 arm); individuals with spinal cord injuries at levels T4 to L5 (upper extremity motor function of at least 4/5 in both arms), and individuals with spinal cord injuries at levels of C7 to T3 (ASIA D with upper extremity motor function of at least 4/5 in both arms)

In 2022, Atalante® (Wandercraft SAS) was cleared for marketing by the FDA through the 510(k) process (K221859). The Indego was the predicate device. Atalante is intended to enable individuals (>18 years of age, able to tolerate a stand-up position) with hemiplegia due to cerebrovascular accident to perform ambulatory functions and mobility exercises, hands-free, in rehabilitation institutions under the supervision of a trained operator.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

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

HCPCS:

E1399	Durable medical equipment, miscellaneous
K1007	Bilateral hip, knee, ankle, foot device, powered, includes pelvic component, single or double upright(s), knee joints any type, with or without ankle joints any type, includes all components and accessories, motors, microprocessors, sensors

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POLICY HISTORY:

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Medical Policy Group, March 2016
Medical Policy Group, March 2017
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