Molina Clinical Policy
Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities (ReWalk): Policy No. 244

Last Approval: 10/12/2023
Next Review Due By: October 2024

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

This policy describes addresses the use of a powered exoskeleton for ambulation in patients with lower-limb disabilities on individuals who have lost the ability to ambulate independently.

An exoskeleton is an external structure with joints and linkages that can be thought of as wearable robots constructed around the shape and function of the human body. A powered exoskeleton, as defined in this evidence review, is an exoskeleton-like framework worn by a human that contains a power source that provides energy for limb movement. **Robotic lower body exoskeletons** are designed to enable individuals with lost lower limb function to walk independently. When worn, the device consists of an upper-body harness, lower-limb braces, motorized joints, ground-force sensors, a tilt sensor, and a backpack containing a computerized controller and rechargeable battery. Using a wrist-worn wireless remote control, the user commands the device to stand, sit, or walk. The user is secured with the device at the waist, along each lower extremity, and at the feet. Additionally, standard crutches are used to maintain stability.

Regulatory Status

The United States Food and Drug Administration (FDA) approved several robotic lower body exoskeleton devices via the 510(k) clearance **(FDA product code: PHL)** with a classification of **Class II** (considered higher risk than Class I devices and require greater regulatory controls to provide reasonable assurance of safety and effectiveness prior to US marketing).

There are several FDA approved robotic lower body exoskeleton devices on the market, including the ReWalk exoskeleton, Ekso, Ekso GT, Indego, and ExoAtlet-II. The FDA-approved indications for these devices include patients with hemiplegia and paraplegia due to spinal cord injury (SCI), multiple sclerosis, or stroke. Ambulation with the assistance of an exoskeleton requires that the patient be accompanied by a caregiver who has received specialized training. **NOTE:** Brand names are used for reference purposes only and are not intended to represent an exhaustive list of all accessible devices.

The FDA has approved two motorized exoskeletons for use in the home:

- ReWalk™
- Indego®

ReWalk™ was the first exoskeleton to receive FDA approval in 2014 with a de novo 510(k) classification. As the number and type of exoskeleton devices making their way to market increased the FDA developed a new classification that applies to eWalk and its generic equivalents. The current ReWalk™ Personal (K160987) device orthotically fits over the lower limbs and part of the upper body and is intended to enable individuals with SCI at levels T4 to L5 to perform ambulatory functions with the supervision of a specially trained companion. In March 2023, the ReWalk™ Personal Exoskeleton received approval from the FDA for use on stairs and curbs in the United States.
The following characteristics should be present in candidates for the device:

- 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)

While the current ReWalk Personal System (K160987) was approved in 2016 the original ReWalk device was the first exoskeleton to receive FDA approval in 2014. These devices were developed for use in the home and in the community are also utilized in clinical rehabilitation settings.

ReWalk ReStore™ (K190337) is a portable, lightweight exo-suit that was approved in 2019 for the treatment of people with stroke-related lower limb disability.

EksoNR (K220988) was originally authorized for exoskeleton marketing in 2016and is designed to perform ambulatory functions in a clinical setting under the supervision of a trained physical therapist for the following populations: individuals with hemiplegia due to stroke and individuals with SCIs at levels C7 to L5. In June 2022 the EksoNR (K200574) became the first exoskeleton approved for patients with multiple sclerosis.

ExoAtlet-II (K201473) received FDA approval in 2021 for use under the supervision of a trained physical therapist in rehabilitation clinics to perform ambulatory functions for individuals with SCI at levels T4 to L5 or C7 to T3 and with upper extremity motor function at least 4/5 in both arms.

Indego (K173530) received FDA approval in 2016 and is a powered hip-knee exoskeleton that enables patients with spinal cord injuries T4 and below to ambulate. This device can be used in rehabilitation centers and for home or personal use.

HAL for Medical Use (Lower Limb Type) (K201559) was authorized by the FDA in 2018 and is classified by the FDA under both Neurological Devices §21 CFR 882.5050 and Physical Medical Devices §21 CFR 890.3480 categories. The HAL is intended for use by patients with spinal cord damage at levels C4 to L5 (ASIA C, ASIA D) and T11 to L5 (ASIA A with Zones of Partial Preservation, ASIA B) in medical facilities.

Keeogo (K201539) exoskeleton was approved by the FDA in 2020 and is intended for use in stroke patients undergoing rehabilitation.

Phoenix Suit X (K183152) was approved by the FDA in 2019 and is a lightweight exoskeleton designed for clinical rehabilitation for patients with lower limb injuries.

COVERAGE POLICY

The robotic lower body exoskeleton devices (e.g., ReWalk™; Ekso™/Ekso GT™; Indego; ExoAtlet-II; HAL; Keeogo; Phoenix Suit X) wearable lower-limb robotic exoskeleton **is considered experimental, investigational, and unproven** for use in lower limb paraplegia due to insufficient evidence in the high-quality peer-reviewed medical literature.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The clinical utility and beneficial health outcomes of robotic lower body exoskeleton devices is primarily limited to small

studies or case series. Insufficient evidence exists to assess safety (outside of a medical or institutional setting, such as the risk of tripping and falling), long-term durability, tolerability, or improvements in net health outcomes.

ReWalk™

There is a general lack of independent published clinical data available regarding the ReWalk exoskeleton. Recent studies are limited in scope, duration, sample size, lack of control groups, are noncomparative, and nonrandomized making determination of appropriate patients who have potential to benefit from this device challenging. Due to insufficient current information supporting the use of the ReWalk Personal 6.0 exoskeleton, particularly outside of an institutional setting, requires further research to support widespread use of this device.

Kwon et al. (2020) compared the ReWalk robot with knee-ankle-foot orthosis (KAFO) in 13 paraplegic patients with SCI. Patients were trained with either the ReWalk robot or the KAFO for four weeks and a total of 20 sessions. After a two-week wash-out period patients were trained on the alternate device for the same time and number of sessions. During all trials, the patients had two evaluations, one after two-weeks and again at the four-week conclusion of each device trial. The evaluations for each device included the six-minute walking test and 30-minute walking test. Other variables assessed were walking distance, velocity, and cadence. Energy expenditure including heart rate, maximal heart rate, physiologic cost index, oxygen consumption, metabolic equivalents, and energy efficiency were assessed at all walking intervals. Only ten patients completed the study, limiting application of the study results. While the ReWalk enabled patients to ambulate with lower energy consumption than the KAFO, it did not receive higher patient approval ratings. There were also no differences between the two devices for usability, walking distance, or speed. The ReWalk was not superior to the KAFO in terms of safety, efficacy, efficiency, or patient satisfaction.

Ilse et al. (2022) conducted a prospective single-group pre-post study of 21 patients with chronic (>6 months) complete SCI who had received prior treatment at a rehabilitation center in the Netherlands. The study started with 25 patients and concluded with four patients not completing the program. Reasons identified for incompletion of the study were inability to learn basic exoskeleton skills, hematoma development in the sacral area, shoulder pain, and fractured distal tibia. All patients who completed the study participated in 24 training sessions over an eight-week period using the ReWalk exoskeleton. The study assessed quality of life (QoL) scores with the Short Form-36 with Walk Wheel modification pre-post exoskeleton training. Secondary outcomes identified included eight SF-36 subdomains. Patients reported significant improvement with bodily pain, social functioning, mental health, and general health perception. Researchers identified that the actual participation in the training sessions may be a factor in overall improvement in mood and QoL for some patients. Bowel management, hip extension, knee extension, ankle dorsiflexion, or spasticity did not improve post ReWalk exoskeleton training. Study results were limited due to lack of a control group, short length of time, and no exoskeleton availability outside of the rehabilitation center. Post-SCI development of secondary health complications including osteoporosis, cardiovascular disease, pressure ulcers, bladder and bowel malfunction, infections, joint contractures, and increased spasticity related to immobility were unable to be assessed on patients due to the constraints of the study. Currently it is unclear how power exoskeletons can be integrated into the treatment of patients with complete and incomplete SCI. Further research is needed to determine the specific type of patient that will benefit from adding the ReWalk exoskeleton as part of a long-term plan of care.

Indego®

The Indego exoskeleton received initial FDA approval in 2016 for use with patients who have sustained a SCI for clinical and home use. In 2018 the FDA expanded the use of the Indego for rehabilitation with stroke patients. Currently clinical trials for the Indego exoskeleton are extremely limited, especially for use in patient's post-stroke. Further research is needed to determine if the Indego exoskeleton is effective in treating functional ambulation for both SCI and stroke patients.

Tefertiller et al. (2017) published the results of a case series study that included 32 participants with T4 and lower SCI. All participants received training sessions with the Indego device 3 times per week for 8 weeks, with a single follow-up phone call one week after the training sessions ended. The trial was completed by all participants. There were 11 documented device-related adverse events, including minor skin abrasions, joint swelling, and bruises. A trochanteric blister and an ankle sprain were the only two moderate adverse events. There were no changes in mid-study and final measures of indoor and outdoor 10MWT speeds (p=0.081 and p=0.62, respectively). On the 10MWT, average indoor walking speed improved by 0.06 m/s (SD=0.07) from mid-study to end assessments. Outdoor walking speed increased by 0.05 m/s (standard deviation = 0.08). Walking distance on the 6MWT increased for all participants, with an average of 151 m from mid-study to final assessment.

Ekso (version 1.1) and Ekso GT (version 1.2)

Bach Baunsgaard et al. (2018) reported the results of a case series study of 52 participants with SCI who were evaluated using the Ekso (n=8) and Ekso GT (n=44) devices. Participants had either sustained a complete motor injury from C7 to L2 or had incomplete motor damage from C1 to L2. The study included gait training sessions scheduled 3 times per week for 8 weeks, followed by 4 weeks of follow-up. The analysis included only participants who attended at least 16 of the 24 scheduled sessions. Eight participants (15.4%) withdrew from the study, and one was eliminated due to spasticity unrelated to the medication, 42 evaluable participants (80.8%) completed the study in the final analysis. Time to rise from a seated position, 10MWT, and the number of steps taken all increased considerably throughout the 8-week training period (p0.001 for all measures). As evaluated by the Borg Scale, the rate of perceived exertion also increased significantly (p=0.001). In the group of newly injured patients (less than one year since injury), the number of those with gait function rose from 5 to 14 after 8 weeks and to 15 after an additional 4 weeks. At the time of follow-up, a single participant in the chronically damaged group (less than one year since injury) had acquired gait function. No significant adverse events were reported, but "a number of skin concerns" were noted. They concluded that training with Ekso and Ekso GT was safe and viable in a heterogeneous group of SCI patients and may improve gait function and balance.

Molteni et al. (2017) presented the first study on powered exoskeletons, which included 23 stroke patients who utilized the Ekso device in 12 one-hour sessions spread over four weeks (3 sessions per week). The authors stratified their data by subject condition, with 12 subacute (<180 days from the acute event) and 11 chronic (>180 days) cases. Motricity index (MI) total scores improved significantly after 6 and 12 weeks in the subacute group. MI measurements for the hip and knee at 6 and 12 weeks likewise revealed substantial benefits. At 12 weeks, there were significant improvements in the ankle level of MI. The Trunk Control Test (TCT) revealed substantial changes at 6 and 12 weeks. The Functional Ambulation Scale (FAC) had comparable outcomes. Two once immobile patients attained the ability to ambulate. The 10MWT and the number of steps did not show any meaningful improvement. In this group, walking velocity and the 6MWT improved significantly at 6 and 12 weeks. The Ashworth scale, which evaluates lower limb spasticity, did not reveal any significant improvements in the chronic group. The total MI score improved significantly at 6 and 12 weeks only at the hip, but not at the knee or ankle. There were no major changes reported for the TCT, the 10MWT, or the actions implemented. At 12 weeks, FAC findings improved significantly, as did walking velocity at both time intervals and 6MWT outcomes.

Karelis et al., (2017) performed a small cohort study with 5 participants with traumatic C7-T10 SCI and mild spasticity. All participants went through a 6-week training phase that included three 3-hour training sessions per week with the Ekso device. Following the completion of the training sessions, no changes in the American Spinal Injury Association Impairment Scale (AIS) were noted. Significant changes in leg and appendicular lean body mass and total leg and appendicular fat mass were observed. The total BMI climbed noticeably. There are no reports of significant injuries.

Sczesny-Kaiser et al. (2019) published the results of the HALESTRO study (HAL-Exoskeleton STROke study). 18 individuals with partial hemiparesis due to a stroke were enrolled for 6 weeks of HAL®-assisted (Cyberdyne, Tsukuba, Japan), supervised, body weight supported treadmill training (BWSTT) exercise. In this crossover trial, participants also underwent six weeks of conventional physiotherapy (CPT). There were no statistically significant differences between the HAL-BWSTT group and the CPT group for the 10MWT (p=0.071), 6MWT (p=0.840), or TUG (p=0.835). In comparison to CPT, the authors found that HAL-BWSTT did not significantly enhance walking function or balance. There is potential in the combination of therapies; however additional studies are required to evaluate health outcomes. Compared to the standard of care, the trial was small and lacked the necessary follow-up to determine if the increase in motor capacities was durable or sustained.

Systematic Review and Meta-Analysis

Zhang et al. (2023) evaluated walking efficiency in SCI patients utilizing a lower limb exoskeleton compared to mechanical gait orthosis. Researchers extracted data to complete a systematic review of walking efficiency comparing a powered exoskeleton and non-powered mechanical gait orthosis. They found that data synthesis using meta-analysis was not possible due to inconsistencies in study design, methodologies, and outcome measurements. Review of 11 trials representing 14 different orthotics were evaluated, but only general information was obtained. Overall walking efficiency in SCI patients was more effective on improving gait performance when using a powered lower limb

exoskeleton, but evidence was limited. Meaningful conclusions were unable to be reached due to the need for more high-quality studies comparing larger groups of patients for longer periods of time. While researchers have identified the complications SCI patients develop due to sedentary lifestyles, it is not clear how robotic exoskeletons will impact future treatment. Randomized control trials are needed to determine when and how robotic exoskeletons can improve treatment for patients with SCI.

Moucheboeuf et al. (2020) conducted a review of all randomized controlled trials investigating exoskeletons in adult patients with stroke from inception to November 2019. Researchers included 33 studies representing 1466 participants. Information was analyzed by subgroups of intervention including physiotherapy alone, physiotherapy combined with body-weight support training, biofeedback, and robot-gait training. Researchers concluded that intervention with body-weight support training, physiotherapy, and robot-gait training combined was more efficient than traditional physiotherapy alone in improving gait speed (+0.09m/s, 95% confidence interval 0.03 to 0.15; p=0.002), FAC scores (+0.51, 95% confidence interval 0.07 to 0.95; p= 0.022), and BBS scores (+4.16, 95% confidence interval 2.60 to 5.71; p=0.000). Researchers felt that these results were underestimated by the attrition bias of studies when meta-regression analysis was performed. Study limitations include heterogenicity of factors including device training techniques used across patients, baseline level of function and physical status of patients prior to onset of condition, severity of condition prior to intervention, rehabilitation intensity, and data collection and extraction methods employed across studies. Researchers recommended that future research should include tightly controlled training regimens in order to develop optimal rehabilitation program protocol.

National and Specialty Organizations

The **American Physical Therapy Association** published guidelines with recommendations for the improvement of locomotor function in ambulatory patients following brain injury, stroke, or incomplete SCI in 2020 (Hornby 2020). The guidelines discourage the use of powered exoskeletons for usage on a treadmill or elliptical to improve walking speed or distance following an acute-onset central nervous system injury in patients who are more than six months post-injury due to minimal benefit, increased costs, and increased time.

The **American Heart Association and the American Stroke Association** published guidelines for adult stroke rehabilitation and recovery in 2016 (Winstein 2016). The guidelines addressed the use of robotic and electromechanics-assisted training devices, and concluded that "Overall, although robotic therapy remains a promising therapy as an adjunct to conventional gait training, further studies are needed to clarify the optimal device type, training protocols, and patient selection to maximize benefits."

SUPPLEMENTAL INFORMATION

American Spinal Cord Injury Association (ASIA) Impairment Scale: A universal classification tool for SCI based on a standardized sensory and motor assessment, with the most recent revision published in 2019 (ASIA 2019).

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes – N/A

HCPCS (Healthcare Common Procedure Coding System) Code

HCPCS	Description
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
L2999	Lower extremity orthoses, not otherwise specified [when specified as a powered robotic lower body exoskeleton device

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informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/12/2023	Policy reviewed, no changes to criteria. Updated Summary of Medical Evidence and References.
10/12/2022	Policy revised, scope of policy expanded, and title updated from 'Lower-Limb Robotic Exoskeleton (ReWalk- Personal**)** for Paraplegia in Spinal Cord Injury' to 'Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities (ReWalk).' IRO Peer Review by practicing, board-certified physician with a specialty in Pain Management and Physical Medicine and Rehabilitation. Policy revisions expanded to include paraplegia in patients with lower-limb disabilities. Updated Summary of Medical Evidence. Clinical practice guidelines added.
10/13/2021	Policy reviewed, no coverage criteria changes. Updated References and Coding added HCPCS K1007.
09/16/2020	Policy reviewed, no coverage criteria changes. Updated References.
09/18/2019	Policy reviewed, no changes.
03/08/2018	Policy reviewed, no changes to criteria. Updated Summary of Medical Evidence, and References. IRO Peer Review on February 1, 2018, by practicing, board-certified physician with a specialty in Pain Management and Physical Medicine and Rehabilitation.
06/22/2017	Policy reviewed, no changes.
12/14/2016	Policy reviewed, no changes.
12/16/2015	Policy reviewed, no changes.
08/05/2015	New policy.

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