Subject: Lower-limb Robotic Exoskeleton [ReWalk-P (Personal)] for Paraplegia in Spinal Cord Injury		Original Effective Date: 8/5/2015
Policy Number: MCP-244	**Revision Date(s):** 3/8/2018	
Review Date: 12/16/2015, 12/14/2016, 6/22/2017, 3/8/2018, 9/18/2019, 9/16/2020		
MCPC Approval Date: 3/8/2018, 9/18/2019, 9/16/2020		

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.[1]

Contents

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL [19 20]

The ReWalk Robotics (Formerly Argo Medical Technologies Ltd.) is an external, powered, motorized orthosis (powered exoskeleton) used for the purpose of providing ambulation in an individual with paralyzed or weakened limbs. There are two types of devices; the first is the ReWalk I (Institutional) intended for use in rehabilitation facilities, the second is the ReWalk P (personal) intended for home use. The ReWalk orthotically fits to the lower limbs and part of the upper body and 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. The ReWalk-P system includes a lightweight fitted brace for the legs and upper body with motorized hip and knee joints, a backpack containing a computer and rechargeable batteries, an array of upper body motion sensors, and a computer-based wireless control system worn on the patient's wrist. It is worn on top of everyday clothing. The patient may command ReWalk to stand up, sit down, or walk. To begin walking, the ReWalk wearer leans forward. The motion sensors detect a change in torso angle. Computer algorithms guide joint motors to lift and bend the legs moving forward. Balance is maintained by concurrent use of crutches

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 approved the ReWalk-P (Personal) wearable lower-limb robotic exoskeleton for home use on June 26, 2014 via its de novo pathway. FDA-designated de novo devices are low to moderate risk devices that are ineligible for 510(k) review because they are not substantially equivalent to a predicate device. ReWalk-P is indicated for people with paraplegia after a spinal cord injury (SCI) at level 7th thoracic vertebra (T7) to 5th lumbar vertebra (L5). The indications for ReWalk-I also include SCI at levels T4 to T6. [2]

Other powered exoskeleton systems that are in development or are currently used in the rehabilitation setting are: The Ekso System (Ekso Bionics, Richmond, CA) approved for institutional use in rehabilitation.

RECOMMENDATION

The ReWalk-P (Personal) wearable lower-limb robotic exoskeleton is considered experimental, investigational and unproven for use in lower limb paraplegia after spinal cord injury due to insufficient evidence in the peer reviewed medical literature.

SUMMARY OF MEDICAL EVIDENCE [4-18]

There is a paucity of published clinical data on ReWalk. The best available published evidence is limited to 1 controlled clinical trial of 9 patients; [7] several prospective uncontrolled studies of 4-12 patients; [4 5 6 10 12 15 16 17] 2 retrospective uncontrolled studies of 12 patients; [14 18] and a systematic review and meta-analysis. [11] There are no randomized controlled trials (RCT) comparing exoskeletons to wheelchairs. None of the studies were carried out in a home-setting or assessed long-term performance. A summary of the published literature is outlined below.

Esquenazi et al. (2012) conducted a small open, noncomparative, nonrandomized study of the safety and performance of the ReWalk powered exoskeleton. The aim of this study was to assess the safety and performance of ReWalk in 12 individuals with paraplegia due to spinal cord injury to carry out routine ambulatory functions. After training, all subjects were able to independently transfer and walk, without human assistance while using the ReWalk, for at least 50 to 100 m continuously, for a period of at least 5 to 10 mins continuously and with velocities ranging from 0.03 to 0.45 m/sec (mean, 0.25 m/sec). Excluding two subjects with considerably reduced walking abilities, average distances and velocities improved significantly. Some subjects reported improvements in pain, bowel and bladder function, and spasticity during the trial. All subjects had strong positive comments regarding the emotional/psychosocial benefits of the use of ReWalk. The study concluded that ReWalk holds considerable potential as a safe ambulatory powered orthosis for motor-complete thoracic-level spinal cord injury patients. Most subjects achieved a level of walking proficiency close to that needed for limited community ambulation. A high degree of performance variability was observed across individuals. Some of this variability was explained by level of injury, but other factors have not been completely identified. Further development and application of this rehabilitation tool to other diagnoses are expected in the future. [5]

Zelig et al. (2012) performed a small case series observational study that included 6 participants. The objective of the study was to evaluate the safety and tolerance of use of the ReWalk™ exoskeleton ambulation system in people with spinal cord injury. Measures of functional ambulation were also assessed and correlated to neurological spinal cord level, age, and duration since injury. Pain and fatigue were graded by the participants using a visual analogue scale pre- and post-training. Participants completed a 10-statement questionnaire regarding safety, comfort, and secondary medical effects. After being able to walk 100 m, timed up and go, distance walked in 6 minutes and 10-m timed walk were measured. There were no adverse safety events. Use of the system was generally well tolerated, with no increase in pain and a moderate level of fatigue after use. Individuals with lower level of spinal cord injury performed walking more efficiently. Volunteer participants were able to ambulate with the ReWalk™ for a distance of 100 m, with no adverse effects during the course of an average of 13–14 training sessions. The participants were generally positive regarding the use of the system. [10]

Fineberg et al. (2013) conducted a small cross-sectional study to analyze vGRF during powered exoskeleton-assisted walking (ReWalk™: Argo Medical Technologies, Inc, Marlborough, MA, USA) compared with vGRF of able-bodied gait. Six persons with thoracic motor-complete SCI (T1-T11 AIS A/B) and three age-, height-, weight- and gender-matched able-bodied volunteers participated. SCI participants were trained to ambulate over ground using a ReWalk™. vGRF was recorded using the F-Scan™ system (TekScan, Boston, MA, USA). Peak stance average (PSA) was computed from vGRF and normalized across all participants by percent body weight. Peak vGRF was determined for heel strike, mid-stance, and toe-off. Relative linear impulse and harmonic analysis provided quantitative support for analysis of powered exoskeletal gait. Participants with motor-complete SCI, ambulating independently with a ReWalk™, demonstrated mechanical loading magnitudes and patterns similar to able-bodied gait. Harmonic analysis of PSA profile by Fourier transform contrasted frequency of stance phase gait components between able-bodied and powered exoskeleton-assisted walking. Powered exoskeleton-assisted walking in persons with motor-complete SCI generated vGRF similar in magnitude and pattern to that of able-bodied walking. The study suggests the potential for powered exoskeleton-assisted walking to provide a mechanism for mechanical loading to the lower extremities. vGRF

profile can be used to examine both magnitude of loading and gait mechanics of powered exoskeleton-assisted walking among participants of different weight, gait speed, and level of assist. [7]

Benson et al. (2015) performed a longitudinal, prospective, self-controlled feasibility study to assess the feasibility of conducting a well-powered trial evaluating the neurological and functional effects of using an exoskeleton in individuals with chronic spinal cord injury. Out of 60 candidates, ten (17%) were enrolled and five (8%) completed the training program. Primary reasons for not enrolling were ineligibility (n = 24, 40%) and limited interest to engage in a 10-week training program (n = 16, 27%). Five out of ten enrolled subjects experienced grade I/II skin aberrations. While walking speeds were higher and walking distances were longer in all exoskeleton users when compared with non-use, the exoskeleton did generally not meet subjects' high expectations in terms of perceived benefits. The conduct of a controlled trial evaluating the benefits of using exoskeletons that require a lengthy user-commitment to training of individuals with chronic motor complete or incomplete spinal cord injury comes with considerable feasibility challenges. Vigilance is required for preventing and detecting medical complications in spinal cord injury exoskeleton users. [4]

Miller et al. (2016) conducted the first meta-analysis of the available published research on the clinical effectiveness and safety of powered exoskeletons in SCI patients. Main outcomes were analyzed using fixed and random effects meta-analysis models. A total of 14 studies (eight ReWalk™, three Ekso™, two Indego®, and one unspecified exoskeleton) representing 111 patients were included in the analysis. Training programs were typically conducted three times per week, 60-120 minutes per session, for 1-24 weeks. Ten studies utilized flat indoor surfaces for training and four studies incorporated complex training, including walking outdoors, navigating obstacles, climbing and descending stairs, and performing activities of daily living. Following the exoskeleton training program, 76% of patients were able to ambulate with no physical assistance. The weighted mean distance for the 6-minute walk test was 98 m. The physiologic demand of powered exoskeleton-assisted walking was 3.3 metabolic equivalents and rating of perceived exertion was 10 on the Borg 6-20 scale, comparable to self-reported exertion of an able-bodied person walking at 3 miles per hour. Improvements in spasticity and bowel movement regularity were reported in 38% and 61% of patients, respectively. No serious adverse events occurred. The incidence of fall at any time during training was 4.4%, all occurring while tethered using a first-generation exoskeleton and none resulting in injury. The incidence of bone fracture during training was 3.4%. These risks have since been mitigated with newer generation exoskeletons and refinements to patient eligibility criteria. In conclusion, powered exoskeletons allow patients with SCI to safely ambulate in real-world settings at a physical activity intensity conducive to prolonged use and known to yield health benefits. [11]

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
	N/A

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

ICD-9	Description: [For dates of service prior to 10/01/2015]
	Any/All

ICD-10	Description: [For dates of service on or after 10/01/2015]
	Any/All

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Other Resources

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    - Evidence Analysis Research Brief. ReWalk Personal System (ReWalk Robotics) for Home Use in Spinal Cord Injury. July, 2020.
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    - Evidence Analysis. ReWalk Personal System (ReWalk Robotics) for Home Use in Spinal Cord Injury. Nov, 2016. Updated January 25, 2018. Archived 2019.
20. Peer Review: Policy reviewed by AMR practicing physician board certified in Physical Med & Rehab, Pain Management. 2/1/18.

Revision/Review History:

8/5/15: New Policy
12/16/2015, 12/14/2016 & 6/22/2017: Policy reviewed, no changes.
3/8/18: This policy was reviewed and this device remains controversial and experimental. The following sections were updated: summary of medical evidence and references.
9/18/19: Policy reviewed, no changes.
9/16/20: This policy was reviewed and this device remains controversial and experimental. Updated references, added TOC.