Anthem

Medical Policy

Subject: Powered Robotic Lower Body Exoskeleton Devices
Document #: OR-PR.00006
Status: Reviewed

Publish Date: 06/28/2023
Last Review Date: 05/11/2023

Description/Scope

This document addresses the use of powered, robotic lower body exoskeleton devices that may be utilized in the rehabilitation of or for daily use by individuals with neurological disorders that affect an individual's ability to ambulate without assistance.

Note: For information regarding other prosthesis, please see the following:

- CG-DME-13 Lower Limb Prosthesis
- CG-OR-PR-08 Microprocessor Controlled Lower Limb Prosthesis

Position Statement

Investigational and Not Medically Necessary:

The use of a powered, robotic lower body exoskeleton device is considered **investigational and not medically necessary** under all circumstances, including but not limited to the following:

- To enable individuals with spinal cord injury to perform ambulatory functions; **or**
- To assist in the rehabilitation of individuals with spinal cord injury; **or**
- To assist in the rehabilitation of individuals with traumatic brain injury.

Rationale

Clinical trial evidence

Use of lower limb electromechanical exoskeleton devices have been proposed to assist in locomotion and rehabilitation for a variety of conditions, including spinal cord injury (SCI), traumatic brain injury (TBI), stroke, multiple sclerosis (MS), and others. The available scientific evidence addressing the clinical utility of such devices is addressed below.

In a pilot study, Zeilig and colleagues (2012) evaluated the safety and tolerance of the ReWalk™ (ReWalk Robotics, Inc., Marlborough, MA) exoskeleton ambulation suit in a case series of 6 subjects with complete motor SCI between T5 and T12. Subjects averaged 33.2 years of age, weighed less than 100 kilograms (kg), and were 155 to 200 centimeters (cm) in height. All subjects underwent several 50-minute-long training sessions to achieve ambulation with a powered robotic lower body exoskeleton device to walk a 100 meter (m) long path. Following this acclimation, a battery of tests, including timed up and go (TUG), 6-minute walk test (6MWT), and the 10-meter walk test (10MWT) were performed. No falls, skin or joint injuries, cardiovascular events or changes on spine radiographs were reported. Several technical issues related to the device were reported; all were resolved. Use of the system was generally well-tolerated, with no increase in pain and a moderate level of fatigue after use. A total of 3 participants with lower lesions (T9-T12) walked longer distances than the other 3 with higher lesions (T5-T7) (mean 66.3 m vs. mean 22.7 m; $p<0.01$). In the 10MWT, participants with lower levels of injury walked faster than those with higher levels of injury (mean 47 seconds vs. mean 85.7 seconds; $p<0.05$). Level of injury did not influence the results in the TUG or the number of training sessions needed before subjects were ready for testing ($p=0.15$ and $p=0.42$, respectively). In this small sample, age and time from injury did not influence any of the test measures. Individuals with lower level of SCI performed walking more efficiently. The authors concluded that 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 to 14 training sessions. The participants were generally positive regarding the use of the system. The authors stated that the potential benefits of the ReWalk are many, including improved functional mobility, cardiovascular and respiratory status, bone metabolism, and bowel and bladder function, as well as reduction of spasticity and neuropathic pain, but such claims remain unsubstantiated by clinical trial data. The researchers noted that this study did not include individuals with quadriplegia, children, or older adults.

A noncomparative study of 12 paraplegic subjects with thoracic level (T3-T12) SCI evaluated the safety and ability of ReWalk to enable individuals with paraplegia due to SCI to carry out routine ambulatory functions (Esquenazi, 2012). Following approximately 8 weeks of acclimation training involving 24 60- to 90-minute sessions, all subjects were successful in independently transferring and walking in the ReWalk for at least 50 to 100 m continuously, for a period of at least 5 to 10 minutes with velocities ranging from 0.03 to 0.45 m/sec (mean of 0.25 m/sec). Excluding 2 subjects with considerably reduced walking abilities, average distances and velocities improved significantly. 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. Some subjects reported improvements in pain, bowel and bladder function, and spasticity during the trial. No falls, bone fractures, or episodes of autonomic dysreflexia occurred. Of the 12 subjects, 5 had a definite or possible study-related mild to moderate adverse event, including skin abrasions, lightheadedness, and edema of the lower limbs. The authors concluded that the ReWalk system holds considerable potential as a safe, ambulatory powered orthosis for individuals with motor-complete thoracic-level SCI.

In 2013, Esquenazi and colleagues published a randomized comparative trial involving 16 subjects with TBI. This study compared the use of the ReWalk device in treadmill assisted rehabilitation training (n=8) vs. manually assisted treadmill rehabilitation training (n=8). Following training, the average self-selected walking velocity (SSV) increased by 49.8% for the ReWalk group ($p=0.01$) and by 31% for the manual group ($p=0.06$). The average maximal velocity increased by 14.9% for the ReWalk group ($p=0.06$) and by 30.8% for the manual group ($p=0.01$). Step-length asymmetry ratio improved during SSV by 33.1% for the ReWalk group ($p=0.01$) and by 9.1% for the manual group ($p=0.73$). The distance walked increased by 11.7% for the ReWalk group ($p=0.21$) and by 19.3% for the manual group ($p=0.03$). While each group demonstrated benefits from their assigned training method, no differences between groups were reported. The value of the ReWalk system in rehabilitation training following TBI is unclear given these results.

Spungen (2013) reported the results of a pilot study from the Bronx Veterans Affairs Hospital of a trial of the ReWalk system in 7 subjects with paraplegia due to SCI with permanent paralysis and loss of mobility. The study was not published in a peer-reviewed

medical journal, but was made available on a Veterans Affairs website. This pre/post intervention pilot case series was performed to determine the number of sessions and level of assistance needed to execute standing, walking, and stair climbing skills with the ReWalk device. Subjects were studied over an average of 45 ± 20 sessions consisting of 1 to 2 hours of standing and overground ambulation for 3 sessions per week. All 7 participants learned to perform sit-to-stand, stand-to-sit, and ambulation to 50 to 166 m in 6 minutes with no (n=4) to varying (n=3) levels of assistance. Ascending and descending ≥ 5 stairs with assistance was achieved by 4 subjects. These same 4 subjects also achieved some outdoor-specific walking skills. The authors reported that there was no relationship with achievement of exoskeletal-assisted mobility skills and the duration or level of SCI.

A comparative study of 6 subjects with motor-complete SCI and 3 able-bodied volunteers using the ReWalk devices was reported by Fineberg and others in 2013. All subjects underwent 1-2 hours of combined sitting and walking sessions 3 times per week for 5 to 6 months. The objective of the study was to use vertical ground reaction force (vGRF) to show the magnitude and pattern of mechanical loading in subjects during walking using the F-Scanin-shoe pressure mapping system (Tekscan, Inc., South Boston, MA). The investigators measured the pressure imparted to both the left and right feet in all SCI subjects while walking in the ReWalk device and in control subjects during unassisted walking. A total of 3 of the SCI subjects participated in the measurement trials using assistive devices such as walkers and the remaining 3 were unassisted. For measurements of peak stance average (PSA) the assisted SCI group had significantly lower vGRF vs. control subjects ($p<0.05$). No significant difference in PSA was noted between the no-assist SCI group and controls. Significant differences between the assist and no assist SCI groups was also noted, with the no-assist group subjects creating greater VGRF than the assisted subjects ($p=0.010$ for midstance and $p=0.045$ for toe off). The authors concluded that powered exoskeleton-assisted walking in individuals with motor-complete SCI generated vGRF similar in magnitude and pattern to that of able-bodied walking. They suggested these results demonstrated the potential for powered exoskeleton-assisted walking to provide a mechanism for mechanical loading to the lower extremities in individuals with SCI.

Asselin and others (2015) reported the results of a small case series study of 8 non-ambulatory subjects with paraplegia who were trained to ambulate with the ReWalk device. The authors reported that the average value of oxygen uptake (VO_2) during walking with the device was significantly higher in all subjects vs. when sitting and standing ($p<0.001$). Also, the heart rate response during walking with the device was significantly greater vs. when subjects were either sitting or standing ($p<0.001$). These findings are not unexpected, and align with what is commonly known about human physiology. The authors concluded that individuals with paraplegia are able to ambulate efficiently using the powered exoskeleton for overground ambulation, providing potential for functional gain and improved fitness. This study provided no data regarding the safety of the device.

Yang and colleagues (2015) described a cohort study involving 12 SCI subjects evaluated for assisted walking speed while using the ReWalk device and assistive Lofstrand crutches. All subjects underwent 10MWT and 6MWT, with the shortest time for the 10MWT and the furthest distance for the 6MWT counted as the best effort. Over a median of 55 training sessions, 7 of 12 subjects were able to ambulate at greater than or equal to 0.4 m/s. The authors reported an inverse relationship was noted for level of assistance and walking velocity for both the 6MWT ($p<0.009$) and the 10MWT ($p=0.009$). No serious adverse events were reported. There were 13 episodes of mild skin abrasions reported, and all resolved with padding and equipment adjustments.

A case series study involving 16 subjects with SCI was conducted to evaluate mobility outcomes for individuals with SCI following 5 training sessions (Hartigan, 2015). All subjects underwent five 90-minute training sessions with the Indego® exoskeleton device (Parker Hannifin Corporation, Macedonia, OH) followed by the 10MWT and the 6MWT with the Indego devices in addition to an assistive device. Additional outdoor tasks were also evaluated during the training sessions, including walking on sidewalks, up and down Americans with Disabilities Act (ADA) compliant ramps, and over grass. A total of 3 subjects had motor complete quadriplegia (C5-C7 level injury), 5 had upper paraplegia (T1-T8 level injury), and 8 had lower paraplegia (T9-L1 level injury). One-half of the subjects were able to ambulate on both indoor and outdoor surfaces, elevators and ramps, and most used an assistive device and minimal or moderate assistance. The average distance covered during a 6MWT was 64 m for subjects with quadriplegia, 76 m for those with upper paraplegia, and 121 m for those with lower paraplegia. A total of 7 of the subjects were able to place the system on and off independently.

Stampacchia and colleagues (2016) published the findings of a cohort study investigating the impact of the Ekso GT™ exoskeleton system (Ekso Bionics, Inc., Richmond, CA) on pain and spasticity. Study investigators enrolled 21 subjects with partial or complete SCI due to traumatic or non-traumatic lesions. All subjects underwent a single 40-minute session of sitting to standing to walking with the Ekso device in addition to an assistive walking device (rollator). Prior to and after the session, subjects completed a subjective rating scale (1 to 10) measuring both pain and spasticity. Spasticity was further measured with the Modified Ashworth scale (MAS) and the Penn Spasm Frequency Scale (PSFS). Walking behavior was deemed to be homogenous throughout the sample based upon walking time and number of steps taken. Following the walking session, perceived spasticity was improved significantly using a subjective rating scale ($p<0.001$), as well as on the MAS and PSFS scales ($p<0.001$ for both). Overall, perceived pain was not significantly changed, but when looking at the subset of subjects with pain prior to the session, significant pain reductions were reported ($p<0.002$). No correlation was noted between the reduction in pain and the reduction in spasticity.

A second cohort study published in 2016 evaluated the quality of life impact of the institutional version of the ReWalk device on 7 subjects with SCI (Platz, 2016). All subjects underwent a 4- to 5-week intensive inpatient device-training session which included 60 minutes of exoskeleton training 5 days per week in addition to individualized therapeutic exercise regimens as indicated. Training sessions included sit-to-stand, stand-to-sit, 2-arm standing balance, 1-arm standing balance, 10 m walking straight ahead, 10 m walking in a curve, climbing a set of 12 stairs, and 500 m outdoor walk. Evaluations included milestones for these activities and satisfaction with training and device use. With the exception of the last two activities mentioned above, all subjects met the expected milestones. Sit-to-stand and stand-to-sit were achieved by all subjects within two training sessions. Indoor walking was achieved by all subjects within 2 weeks. The majority of subjects were able to achieve these activities, as well as 1- and 2-arm standing balance activities without physical assistance or occasional help. Only 4 subjects achieved climbing the 12 steps. No data was provided for the 500 m walk evaluation. The authors reported a “fair” degree of satisfaction with the training. Pre/post measures of the physical domain of the SF-36v2 indicated significant improvements, but no other domain demonstrated significant changes. No significant adverse events were reported, including falls and cardiovascular events. Skin lesions were reported in 4 subjects, but were resolved with adjustment of the device and discontinuation of the training was not necessary. Mild pain or swelling were reported in 4 subjects. No changes in motor or sensory signs, spasticity or activities of daily living competence were reported.

A third cohort study was published in 2016 by Benson and colleagues. This trial involved 10 subjects with C7-T12 SCI trained to use the ReWalk device in twice weekly session for a total of 20 sessions. Only 5 subjects completed the full trial; 2 decided not to continue with the training, 2 experienced recurrent skin breakdown requiring discontinuation, and a fifth experienced a fractured talus. The mean number of weeks required to complete the 20 sessions for the 5 remaining subjects was 19 weeks. The average number of sessions before a subject was deemed ready for stairs training was 6. Improvements in spasticity were noted in the 2 subjects with mild spasticity prior to training (Ashworth scale -0.70). Over the course of training, all 5 subjects experienced improvements in gait speed, walking distance, speed to standing up, rotating, and sitting. Stair ascent and descent was achieved by 4 subjects. No significant benefits were noted in the 10MWTor the TUG test, however, some improvements were noted in the 6MWT. Measures on the Appraisals of Disability: Primary and Secondary Scale (ADAPASS) showed mixed results, with improvements seen in the primary

scales, but not in any of the six subscales. Results on the Assistive Technology Device Predisposition Assessment (ATD-PA) did not demonstrate significant improvements in functional abilities or personal characteristics.

A meta-analysis of the clinical effectiveness and safety of powered exoskeleton devices was published by Miller and colleagues in 2016. The investigators included 11 studies involving 111 subjects using the ReWalk (8 studies), Ekso (3 studies), and Indego (2 studies) devices. An additional study involved an unspecified device. Considerable heterogeneity was present across studies with regard to methods and duration of training, in addition to outcomes such as ambulatory performance, metabolic demand, and perceived health benefits. No serious adverse events were reported. The incidence of falls during training was 4.4% (n=3), and all falls were reported in the same study (Kozlowski, 2015). The falls were attributed to programming errors in the first generation Ekso device in 2 cases and to a crutch malfunction in the 3rd case. The authors concluded that, “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.” However, this conclusion is weakened by the fact that the majority of studies took place in the investigational setting.

A cohort study involving 5 subjects with traumatic C7-T10 SCI and minimal spasticity was published by Karelis and others in 2017. All subjects underwent a 6-week long training period involving 3, 3-hour long training sessions per week with the Ekso device. No changes in the American Spinal Injury Association Impairment Scale (AIS) were reported following completion of the training sessions. Significant changes were noted for leg and appendicular lean body mass, and total leg and appendicular fat mass. Total BMI increased significantly. No serious injuries were reported.

Kozlowski (2017) reported the findings of the first study involving the use of the ReWalk device in 5 subjects with MS. This cohort study involved individuals with Expanded Disability Status Scale (EDSS) scores ranging from 5.5 to 7.0, who are medically stable, fit the ReWalk device, could tolerate standing for 30 minutes, and it had been at least 1 year since their last relapse. Evaluations were taken at baseline and at weeks 1, 4, 8 (baseline period), 12 and 16 (intervention period) and at week 20 (follow-up). Subjects underwent 3, 30- to 90-minute training sessions per week for a total of 24 sessions. The study originally enrolled 13 subjects, but 2 failed screening and 6 withdrew, either due to transportation issues or device-related pain. A total of 5 subjects completed a minimum of 20 walking sessions. The investigators commented that regression of progress was noted with gaps in the training interval that exceeded 4 days, but losses were usually regained within a single session. Learnability was considered high, with most participants attaining walking and sitting well within the 24-session limit. No serious adverse events were reported, but skin issues were common, with 151 events per 1000 hours of exposure to training. Qualitative postural improvements were reported for 4 of the 5 subjects. No overall improvement was reported with regard to the Neuro-QOL (quality of life) and Patient Reported Outcome Measurement and Information System (PROMIS) tools.

In 2017, Molteni published the results of the first study investigating the use of a powered exoskeleton device in subjects who had experienced a stroke. This study involved 23 subjects who were trained to use the Ekso device in 12, 1-hour long sessions over 4 weeks (3 sessions per week). The authors stratified their findings by subject condition, with 12 subacute (< 180 days from acute event) and 11 chronic (> 180 days from acute event). For the subacute subjects, the total scores on the motricity index (MI) revealed significant improvements at 6 and 12 weeks (p=0.008 and p=0.001, respectively). MI measures for hip and knee at 6 and 12 weeks also demonstrated significant benefits (p=0.008 and p=0.002 for hip, p=0.013 and p=0.008 for knee, respectively). Improvements in the MI ankle level were significant at 12 weeks. The Trunk Control Test (TCT) showed significant changes at both 6 and 12 weeks (p=0.008 and p=0.004, respectively). The Functional Ambulation Scale (FAC) had similar results (p=0.001 for both 6 and 12 weeks). Ambulation was achieved in 2 nonambulatory subjects. No significant improvements were noted in the 10MWT or in the number of steps. Finally, for this group, significant improvements were reported in walking velocity and the 6MWT at both 6 and 12 weeks (p=0.023 and p=0.008 for velocity, respectively and p=0.016 and p=0.004 for 66MWT, respectively). In the chronic group, no significant changes were found on the Ashworth scale, which measures lower limb spasticity. With respect to MI scores, the total score did show significant improvements at 6 and 12 weeks (p=0.016 and p=0.008, respectively), but only at the hip level (p=0.016 for both time points), but not at the knee or ankle levels. No significant changes were reported for the TCT, 10MWT, or steps taken. Findings on the FAC were significantly improved at 12 weeks (p=0.031), walking velocity improved significantly as well at both time points (p=0.016 for both), as did the results of the 6MWT (p=0.016 and p=0.031, respectively).

Tefertiller and others (2017) reported on a case series study involving 32 subjects with T4 and lower SCI. All subjects underwent training sessions with the Indego device 3 times weekly over 8 weeks and a single follow-up phone call 1 week after the completion of the training sessions. All subjects completed the trial. A total of 11 device-related adverse events were reported, including minor skin abrasions, joint edema, and bruising. A total of 2 moderate adverse events occurred, a trochanteric blister and a sprained ankle. No differences between mid-study and final measurements of indoor and outdoor 10MWT speeds were noted (p=0.081 and p=0.62, respectively). On the 10MWT, from the mid-study to final measurements, average indoor walking speed improved by 0.06 m/s (SD=0.07). Outdoor walking speed improved by 0.05 m/s (SD=0.08). Walking distance on the 6MWT from the mid-study to final measurements increased for all participants, with an average 151 m.

Bach Baunsgaard (2018) reported the results of a case series study of 52 subjects with SCI who were evaluated using the Ekso (n=8) and Ekso GT (n=44) devices. Subjects had either motor complete injury from C7 to L2 or motor incomplete injury from C1 to L2. The study involved gait training sessions scheduled 3 times weekly over 8 weeks and then followed for an additional 4 weeks. Subjects completing at least 16 of the 24 scheduled were included in the analysis. A total of 8 subjects (15.4%) dropped out of the study, and another was excluded due to spasticity unassociated with the treatment, leaving 42 evaluable subjects (80.8%) in the final analysis. The authors reported that time to get out of the seated position, 10MWT, and number of steps taken all increased significantly during the 8-week training period (p<0.001 for all measures). Rate of perceived exertion, as measured with the Borg Scale, significantly improved as well (p=0.001). Perhaps most importantly, in the group of recently injured subjects (time since injury < 1 year), the number that had gait function increased from 5 to 14 after the 8-week period, and to 15 after the additional 4-week follow-up period. A single subject in the chronically injured group (time since injury ≥ 1 year) acquired gait function at the time of follow-up. The authors noted no serious adverse events were experienced, but did report “a number of skin issues.” These issues were not further described in the article. They concluded that training with the Ekso and Ekso GT devices was generally safe and feasible in a heterogeneous sample of persons with SCI and that they may provide benefits for gait function and balance.

Hayes and colleagues (2018) published the results of a systematic review of robotic exoskeleton devices used in gait training of individuals with spinal cord injuries. They included 12 studies, including 3 involving overground trials and 9 involving treadmill trials. The primary outcome measures reported were walking speed and walking distance. They reported that the use of treadmill or overground based robotic exoskeleton-assisted gait training did not result in an increase in walking speed beyond that of conventional gait training. Furthermore, they stated that no studies reviewed enabled large enough improvements to enable community ambulation.

In 2019, Sczesny-Kaiser reported the results of the HALESTRO study (HAL-Exoskeleton STROke study). A total of 18 subjects that had incomplete hemiparesis as a result of a stroke were enrolled for 6 weeks of HAL®-assisted (Cyberdyne, Tsukuba, Japan), supervised, body-weight supported treadmill training (BWSTT). The subjects also received conventional physiotherapy (CPT) for 6 weeks in this crossover study. There were no significant differences between the HAL-BWSTT and CPT group for the 10MWT (p=0.071), 6MWT (p=0.840), or TUG, (p=0.835). The authors reported that HAL-BWSTT did not significantly improve walking function or balance abilities when compared with CPT. While the combination of therapies shows promise, further studies are needed to

evaluate net health outcomes. The study was small and lacked sufficient follow-up needed to assess durable or continued improvement in motor capabilities as compared to standard of care.

Ii (2020) published the results of a study involving 36 subjects with hemiparesis post-stroke who underwent gait training using the Welwalk device, who were compared with matched control subject data from a hospital database. Training consisted of 40 minutes of device-based activity 5-7 days a week, in addition to the usual rehabilitation 3 hours a day, for 6 or 7 days per week. The control group underwent only the usual rehabilitation program. The primary outcome was improved efficiency of walking ability, calculated from baseline evaluation to achieving a Functional Independence Measure (FIM)-walk score of 5 using a specified formula. Evaluations were taken every 2 weeks for a total of 8 weeks. Overall, improvement in efficiency of FIM-walk was significantly higher in the exoskeleton group vs. the control group ($p<0.001$). Subjects in the exoskeleton group became able to walk with the device with no assistance in approximately 1.4 weeks, and achieved an FIM-walk score of 5 in approximately 3 weeks. The authors stated their results demonstrated that use of the exoskeleton device successfully improved walking efficiency in subjects with post-stroke hemiparesis in a real-world rehabilitation facility setting.

Xiang and colleagues (2021) reported the results of a single-center, randomized controlled pilot study exploring the effects of exoskeleton-assisted walking (EAW, AIDER [AssItive DEvice for paRalyzed patient] device) on pulmonary function and walking parameters compared to conventional rehabilitation training in individuals with SCI. The study involved 18 individuals, previously diagnosed with an SCI, who were randomized to receive either EAW or conventional training delivered as 50 to 60 minute sessions, 4 times per week for 4 weeks. Regarding pulmonary function parameters after training, significantly greater values were observed for forced vital capacity (FVC, $p=0.041$), FVC% ($p=0.012$), and forced expiratory volume in 1 second (FEV_1, $p=0.013$) in the EAW group compared to the conventional treatment group. Differences in values for forced expiratory flow, peak expiratory flow, and maximal voluntary ventilation were not statistically significant. Only 10 participants completed the final 6MWT, of which 2 were in the conventional treatment group. There was no difference in lower extremity motor score. The results of this study suggest EAW has the potential to improve some pulmonary function parameters among this group of individuals with SCI, although the clinical significance is uncertain. Interpretation of study results is limited by the overall sample size and proportion of participants lost to follow-up.

Androwis (2021) published the results of a randomized controlled pilot study evaluating the effects of 4 weeks of robotic exoskeleton-assisted exercise rehabilitation (REAER) compared to conventional gait training in individuals with substantial disability due to MS. The experimental condition involved supervised and progressive overground walking using the Ekso-GT robotic exoskeleton. The outcomes of interest were the effects of REAER on functional mobility (assessed by TUG), walking endurance (assessed by 6MWT), cognitive processing speed ([CPS], assessed by Symbol Digit Modalities Test [SDMT]), and brain connectivity (assessed by thalamocortical resting-state functional connectivity [RSFC] on fMRI). The study involved 10 individuals with substantial MS-related neurological disability. Although there were large improvements in functional mobility in the REAER group based on effect size estimates, there was no significant between-group difference in functional mobility ($p=0.06$) or walking endurance. There was a significant between-group difference in cognitive processing speed ($p=0.02$) and brain connectivity ($p<0.01$) in favor of the REAER group. Though the improvements in some individuals in this study population are promising, additional evidence in appropriately powered trials of sufficient duration is needed to confirm the durable effects of REAER on mobility and cognition in individuals with substantial MS-related disability.

Berriozabalgoitia and colleagues (2021) reported the results of a randomized controlled trial (RCT) evaluating the use of overground robotic training in addition to a conventional outpatient physical therapy program in individuals with MS. The study involved 36 individuals with Expanded Disability Status Scale score between 4.5 and 7, and the need for assistive devices for walking outdoors. Participants were randomized to a conventional physical therapy program consisting of individualized, weekly, 1-hour sessions (control group, n=14) or conventional therapy plus overground gait training (OR group, n=18). Overground gait training consisted of a twice-weekly, individualized, and progressive intervention for 3 months using the Ekso wearable exoskeleton. The primary outcome was performance on the 10MWT. Secondary variables included the Short Physical Performance Battery, TUG, and Modified Fatigue Impact Scale. There were no statistically significant between-group differences regarding the 10MWT. In the OR group, there was significant improvement on the TUG ($p=0.049$, medium effect size) without an increase in fatigue perception. However, no time per group interactions were observed for any variable.

Evans (2021) published the results of a pilot RCT involving 16 subjects with SCI-related tetraplegia who underwent 24 weeks of either robotic exoskeleton therapy with the Esko GT device or activity-based training (n=8 per group). The exoskeleton group underwent treatment consisting of standing and walking 10 to 50 minutes in the Esko device and between 50 and 1800 steps taken. The control activity-based group treatment consisted of a combination of resistance, cardiovascular, and flexibility training. This group also had the option of receiving gait retraining. The authors reported no statistically significant differences between groups or over time for brachial systolic and diastolic blood pressure, ankle systolic pressure, or ankle brachial pressure index. At 24 weeks, heart rate in the standing position was significantly higher in the control group vs. the exoskeleton group (95.6 beats/min vs. 75.1 beats/min; $p=0.05$). No significant differences in heart rate were reported during the 6-minute arm ergometry test. No statistically significant differences between groups, or over time were reported for heart rate variability indices in the supine or standing positions, or during the 6-minute arm ergometry test. The exoskeleton group had a significant increase in walking distance during the 6MWT from baseline to 24 weeks (68.3 m to 109.9 m).

Sakel (2022) reported the results of a prospective case series study involving 10 subjects with MS who underwent balance training with the Rex Rehab Robot exoskeleton device. The training focused on strengthening leg extensor and abdominal muscles, maintaining an optimal upright posture through standing in the exoskeleton device, and performing dynamic balance exercises. A total of 4 sessions over 1 month were conducted per subject, and measures were taken before and after the completed training series. Statistically significant improvements were reported for 4 subjects based on Berg Balance Scale (BBS) measures, but no overall changes were noted for the study population. Impact of MS on daily lives was improved for 80% of subjects based on Multiple Sclerosis Impact Scale (MSIS-29) measures ($p=0.006$). Similar findings were reported with 70% of subjects having significant improvement on their Health-related Quality of Life Scale (EQ-5D-5L) scores ($p=0.02$). Spasticity, based on Modified Ashworth Scale (MAS) outcomes, was statistically significantly reduced in the left ankle plantar flexors and dorsiflexors and right ankle dorsiflexors. No significant changes were reported on the Modified Falls Efficacy Scale (MFES), Activities-Specific Balance Confidence Scale (ABC), Multiple Sclerosis Walking Scale (MSWS-12), Arm Activity Measure (ArmA), or the Epworth Sleepiness Scale (ESS). No device-related adverse events, including falls, were reported. The clinical relevance of these results is unclear, given the small sample size, short study duration, and absence of a control group.

Rodríguez-Fernández (2022) published the results of a randomized cross-over study involving 10 subjects with SCI who underwent a 10-session, gait training program with both a knee-ankle-foot orthosis and the ABLE Exoskeleton device in succession. Randomization determined which device subjects were started with, and then crossed over to after the initial training and evaluation period ended. Each training period was 5 weeks in duration with 2 sessions per week. Subjects spent a minimum of 30 minutes per session doing sit-to-stand and stand-to-sit transitions, and standing and walking using the designated devices and the aid of a walker. There was a 2-week resting period between the use of each device. No significant differences were found between the groups with regard to distance covered during the 6MWT, time needed to complete the TUG, and gait speed during the 10MWT. As would be expected with the use of a powered assistive device, step length, range of motion (ROM) of both knee and hip joint, and ankle

circumduction were significantly improved in the exoskeleton group vs. the control group (p=0.037, p=0.002, p=0.004, and p=0.014, respectively). No significant differences between groups were reported for metabolic cost of transport (MCoT) and the intensity of physical activity as a percentage of peak oxygen uptake (%VO_{2peak}) during the 6MWT. As with similar trials previously discussed, the clinical relevance of these results is unclear, being from such an underpowered, short-term study.

van Nes (2022) reported on a prospective single-group pre-post study involving 21 subjects with SCI who underwent 24 1.5-hour training sessions with the ReWalk device over 8 weeks. All subjects used crutches during their training sessions. The researchers reported significant improvement post therapy vs. baseline on QOL Short Form-36 with Walk Wheel modification (SF-36ww) measures (p=0.02). Significant improvements were reported on SF-36 subdomains for bodily pain, social functioning, mental health, and general health perception. No significant changes were reported with regard to fecal or urinary incontinence, satisfaction with bowel management, time used for bowel management, or passive ROM measures. No mention of adverse events or complications was made. The overall clinical relevance of these results requires additional study.

Edwards (2022) published the results of an RCT involving 25 subjects with incomplete SCI who underwent a 12-week gait training program. Subjects were assigned on a 2:2:1 basis to one of the following: 1) 45-minute training session with the Esko GT exoskeleton 3 times a week, including overground training without bodyweight support when possible, 2) active control training involving 45-minute bodyweight supported treadmill training and overground training without bodyweight support when possible, and 3) passive control in which subjects continued daily activities with no new gait training, mobility therapy, or new medications related to the condition under study. The final study included 9 exoskeleton subjects, 10 active control subjects, and 6 passive control subjects. The results at 12 weeks revealed no significant between-group difference for self-selected gait speed (p>0.05), with all groups having improvements (51% for the exoskeleton group, 32% for the active control group, and 14% for the passive control group). Similar findings were reported for maximum gait speed at 12 weeks (44% for the exoskeleton group, 50% for the active control group, and 14% for the passive control group; between-group comparisons p>0.05). The group with the highest proportion of change in clinical ambulation category was the exoskeleton group (5 of 9 subjects). The active control group followed with 3 of 10 subjects and the passive control group with no changes (between-group difference in proportions p<0.05). No significant differences were reported between groups for the 6MWT or the TUG. A majority of both exoskeleton subjects (8/9) and active control subjects (7/10) had no change in type of assistive device used throughout the study period. No change in assistive device type was reported for the passive control group. Three serious adverse events were reported: two urinary tract infections deemed to be unrelated to the device, and one active control group subject was admitted to the hospital with lower extremity numbness and a UTI. The numbness was deemed to be “possibly related” to the bodyweight supported treadmill training. No falls were reported. Non-serious adverse events deemed “possibly” or “probably” related to the device or training process included upper and lower extremity musculoskeletal issues (8 exoskeleton group and 4 active control group), increased spasticity (3 exoskeleton group and 1 active control group), skin issues (5 exoskeleton group and 1 active control group); and 1 visceral issue (1 exoskeleton group). The authors concluded that use of the exoskeleton device may improve ambulatory status, but “While generally safe and tolerable, larger gains in ambulation might be associated with higher risk for non-serious adverse events.”

Just (2022) reported on a case series study evaluating the use of the MyoSuit in assisted mobilization in 20 subjects with advanced heart failure (New York Heart Association [NYHA] class III heart failure). Subjects underwent either a single session of activities of daily living evaluation (ADLs, n=10) or a single, standardized, 60-minute rehabilitation exercise session (n=10) with and without the exoskeleton device. The ADL session included evaluations of subjects doing a 6MWD, standing, sitting down on a chair, standing up from a chair, and climbing stairs. The exercise session included dynamic walking training, combined with resistance exercise of the upper body, and dynamic and static balance training. The mean total walk distance of all subjects without and with robotic assistance was 364.0 m and 325.2 m, respectively (p=0.241). No significant differences were reported for either the ADL or exercise groups with regard to rates of perceived exertion with or without the exoskeleton (p=0.932). No adverse events occurred during the study. The results of this limited study appear to indicate no benefit to the use of the MyoSuit for individuals with advanced heart failure.

Shackleton (2022) conducted a secondary analysis of the previously discussed study conducted by Evans (2021). This study evaluated the impact of the Esko GT device on bone mineral density (BMD) in 16 incomplete SCI subjects who underwent 60-minute activity-based training sessions 3 times per week for a total of 24 weeks. No significant changes in spinal BMD were reported for either the exoskeleton or control groups (p=0.86). However, a significant decrease in hip and femoral neck BMD was reported in the control group (p=0.04 for hip and p=0.04 for femoral neck). A significant 7% increase in arm fat-free soft tissue mass (FFSTM) was reported in both groups (p<0.01 for both). No change in leg FFSTM occurred in either group (p=0.32). The control group showed a significant 15% decrease in visceral adipose tissue (p=0.04) and 13% decrease in gynoid fat mass (p<0.01). No similar findings were reported for the exoskeleton group. The authors concluded that exoskeleton-based training aided in the prevention of spine, hip and femoral neck BMD. The findings of this trial should be further evaluated.

McGibbon (2022) described the results of a randomized two-stage cross-over study involving 24 subjects with unilateral knee osteoarthritis who underwent evaluation of both in-clinic and home use of the Keeogo™ exoskeleton over 6 weeks. Subjects were randomly assigned to undergo evaluations in both settings both with and without the use of the exoskeleton device. No significant difference in 6MWT scores were reported between the exoskeleton and control groups in either setting (p=0.052 for clinic and p=0.237 for home). In the timed stair test, times for ascent and descent were both longer in the control group (p<0.001 for ascent and p=0.002 for descent). A similar result was reported for the TUG, with the exoskeleton group having faster times (p=0.004). At the completion of the study, significant improvements were reported for SF36 Energy/Vitality measure (p=0.005), SF36 General Health measure (p=0.043), Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain (p=0.004) and WOMAC function (p=0.003). A total of four adverse events deemed related to the exoskeleton device were reported, including faulty battery charge causing device failure, thigh muscle pain remedied by adjusting device fit, and knee and ankle pain. The authors conclude that there were no immediate benefits to the use of the exoskeleton device, but cumulative effects were detected.

Thimabut (2022) conducted a prospective, assessor-blinded, RCT involving 26 subjects with stroke-related hemiplegia who received 30 physiotherapy and ambulation training sessions (60 minutes each) 5 days a week for 6 weeks, with or without the Welwalk exoskeleton device (n=13 per group). The average age of subjects in the exoskeleton group was 52.8 years vs 62.8 years in the control group (p=0.009) and there were 6 male subjects (46.2%) in the Welwalk group vs. 10 (76.9%) in the control group (p=0.02). This is relevant because the investigators observed that in a multivariable analysis of the exoskeleton group, age and sex were the only significant covariables (p=0.003 and p=0.035, respectively). Both groups showed statistically significant improvement from baseline in FIM-walk scale measures (p≤0.001 at both the 15^{th} and 30^{th} session for both groups). Between-group comparisons showed that the exoskeleton group had a significantly higher FIM-walk score than the control group at the end of the 15^{th} session (p=0.012). However, that difference disappeared at the end of the 30^{th} session (p=0.070). Both groups had significant improvements in 6MWT results (p<0.05), but no difference between groups was reported. The Barthel ADL index indicated significantly more improvement in ADLs in the exoskeleton group vs. the control group (p<0.001). Finally, gait symmetry ratio at the completion of the study was significantly different between groups (p=0.044). There were no significant differences in other gait parameters. The authors concluded that their results demonstrated early improvements in walking ability and Barthel ADL index with the Welwalk device. Additional investigations into the benefits of this device are warranted to support these findings and evaluate long-term

benefits. Only the EQ-5D score was significantly higher in the exoskeleton group at the end of the trial (p=0.028).

Yoo (2023) reported the results of an RCT involving 25 subjects recovering from subacute stroke. All subjects participated in a conventional daily stroke neurorehabilitation program (90 minutes/day, 5 days per week, for 4 weeks). In addition, subjects were randomized to receive additional 12 sessions of gait training (30 minutes/day, 3 days per week, for 4 weeks) with either the ExoAtlet Medy exoskeleton device (n=16) or standard physiotherapy (n=9). Of the original 25 subjects randomized, only 17 (9 in the exoskeleton group and 8 in the control group), completed the study. At the completion of the study, no significant differences between groups were reported for the primary outcome, change in functional ambulatory category (FAC). Both groups demonstrated significant improvements in the BBS, K-MBI (Korean version of the modified Barthel index), and EQ-5D scores after 12 gait training sessions ($p<0.05$). Additionally, exoskeleton group subjects had significant improvements in the FAC, TUG, and 10MWT vs. the control group, which had no significant improvements in those measures. In the between-group analysis, the improvements in the FAC and EQ-5D were statistically higher in the exoskeleton group vs. the control group ($p=0.046$ and $p<0.015$, respectively). No significant improvement was observed in pulmonary function in either group. No severe adverse events were reported. This study found early benefits to the use of exoskeleton device in some, but not all assessed outcomes for individuals with subacute stroke undergoing rehabilitation; additional long-term study is warranted.

Pan (2023) published a prospective case series study of 5 subjects with post-stroke hemiparesis who underwent walking trials using the Gait Enhancing and Motivating System with additional thoracolumbar interface. Three subjects were classified as community ambulators, and 2 subjects were classified as limited community ambulators. The purpose of the study was to evaluate the effect of different hip exoskeleton assistance strategies on gait function and gait biomechanics. The investigators' central hypothesis was that individuals with hemiparesis due to stroke would have increased self-selected walking speed using a powered hip exoskeleton that applies bilateral assistance to both the paretic and non-paretic limbs vs. the paretic or non-paretic limb only. The protocol required the subjects to complete 4 passes across a 6-meter walkway at their self-selected walking speed, and then walk on an instrumented split-belt treadmill at 80% of the overground self-selected walking speed for 1 minute. Subjects were then asked to wear and acclimate to the exoskeleton, and allow the device to be calibrated to the individual before engaging in a second session. Subjects then walked on a treadmill for 1 minute with the exoskeleton set with one of 16 different combinations of assistance magnitude for both the paretic and non-paretic limbs. Subjects then completed 4 passes on the 6-meter walkway with the same assistance condition. The authors reported that the exoskeleton significantly influenced self-selected walking speed ($p<0.001$). Of the assistance conditions tested, 10 of the 16 resulted in changes that exceeded the minimal clinically important difference, defined as an increase of 0.1 m/s for self-selected walking speed, corresponding to about a 12.4% change with respect to the baseline. All assistance strategies resulted in a greater paretic-limb step length increase vs. baseline than the minimal detectable change, defined as 2.62 cm and 2.11 cm for the paretic and non-paretic step length, respectively. Anterior ground reaction force (AGRF) in the non-paretic limb was greater than the minimal clinically important difference of 0.8% BW (BW was undefined) in only one setting. For the paretic limb, 6 of the 10 settings resulted in a greater increase in AGRF than the minimal clinically important difference threshold. The authors concluded that when compared to walking without a device, the use of a hip exoskeleton device improved subjects self-selected overground walking speed with both bilateral and unilateral assistance strategies ($p<0.05$ for both). They added that both bilateral and unilateral assistance strategies significantly improved step length in both paretic and non-paretic limbs ($p<0.05$ for both). The clinical utility of these findings and association with health outcomes remains to be elucidated.

Authoritative organization information

The American Heart Association and the American Stroke Association published guidelines for adult stroke rehabilitation and recovery in 2016 (Winstein, 2016). This document 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."

In 2017, the Cochrane Library published a report assessing electromechanical-assisted training for walking after stroke (Mehrholz, 2017). This report concluded:

> People who receive electromechanical-assisted gait training in combination with physiotherapy after stroke are more likely to achieve independent walking than people who receive gait training without these devices. We concluded that seven patients need to be treated to prevent one dependency in walking. Specifically, people in the first three months after stroke and those who are not able to walk seem to benefit most from this type of intervention. The role of the type of device is still not clear. Further research should consist of large definitive pragmatic phase III trials undertaken to address specific questions about the most effective frequency and duration of electromechanical-assisted gait training as well as how long any benefit may last.

Conclusion

Published evidence addressing the clinical utility and beneficial health outcomes of robotic lower body exoskeleton devices is limited to multiple studies involving short-term follow-up duration investigating a wide array of outcomes, ranging from physical performance tests (for example, 6MWD and TUG), physiological measures (for example, body composition, bladder and bowel function, BMD, and cardiopulmonary function), and physical and functional outcomes (for example, pain, spasticity, ADLs). To date, available studies have been limited to the research setting; results have also been highly variable, with some studies reporting statistically significant benefits and others not. The clinical significance of many of the most commonly reported measures such as 6MWD, TUG, etc., have not clearly demonstrated clinical utility with regards to use of robotic lower body exoskeleton devices. Other reported endpoints, less commonly reported, such as change in BMD, improvement in ADLs and cardiopulmonary function, and decrease in pain and spasticity, may provide a better reflection of these devices in terms of net health benefit. To date, such data has not been adequately addressed in the published literature. Joint pain and edema, falls, skin abrasions, and other complications have been reported in association with robotic lower body exoskeleton devices. It is also unclear if the proposed benefits of using robotic lower body exoskeleton devices are durable, due to a lack of long-term study results. Data from well-designed studies of sufficient duration to evaluate durable outcomes including functional and physiologic endpoints using standardized measures are instrumental in helping to understand the overall place in care and identification of what populations are most likely to derive benefit from robotic lower body exoskeleton devices.

Background/Overview

Robotic lower body exoskeleton devices are intended to allow individuals with loss of lower limb function to ambulate on their own. When used, the device is worn outside clothing and consists of an upper-body harness, lower-limb braces, motorized joints, ground-force sensors, a tilt sensor, a locomotion-mode selector, and a backpack carrying a computerized controller and rechargeable battery. Using a wireless remote control worn on the wrist, the user commands the device to stand up, sit down, or walk. The device is strapped to the user at the waist, alongside each lower limb, and at the feet. Ordinary crutches are also utilized to help maintain stability.

There are several FDA approved robotic lower body exoskeleton devices on the market, including the ReWalk exoskeleton, Ekso, Ekso GT, Indego, and the ExoAtlet-II (ExoAtlet Asia Co. Ltd., Denver, CO). The FDA-approved indications for these devices include

use by individuals with hemi- and paraplegia due to spinal cord injuries or stroke when accompanied by a specially trained caregiver. They may also be used in rehabilitation institutions. None of these types of devices are intended for sports or climbing stairs. For some of these devices, candidates must retain upper-limb strength and mobility to manage stabilizing crutches.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

When services are Investigational and Not Medically Necessary:

HCPCS

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]

ICD-10 Diagnosis

	All diagnoses

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Government Agency, Medical Society, and Other Authoritative Publications:

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	05/11/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, Background, References, and Index sections.
Reviewed	05/12/2022	MPTAC review. Updated Rationale, Background, References, and Index sections.
Reviewed	05/13/2021	MPTAC review. Updated Rationale and References sections.
	10/01/2020	Updated Coding section with 10/01/2020 HCPCS changes; added K1007.
Reviewed	05/14/2020	MPTAC review. Updated Rationale, References, and Index sections.
Reviewed	08/22/2019	MPTAC review. Updated Rationale and References sections.
Reviewed	09/13/2018	MPTAC review. Updated Rationale and References sections.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale and References sections.
Reviewed	11/03/2016	MPTAC review. Updated References section.
Reviewed	11/05/2015	MPTAC review. Updated Rationale and Reference sections. Removed ICD-9 codes from Coding section.
New	11/13/2014	MPTAC review. Initial document development.

Applicable to Commercial HMO members in California: When a medical policy states a procedure or treatment is investigational, PMGs should not approve or deny the request. Instead, please fax the request to Anthem Blue Cross Grievance and Appeals at fax # 818-234-2767 or 818-234-3824. For questions, call G&A at 1-800-365-0609 and ask to speak with the Investigational Review Nurse.

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 eligibility for coverage. The member's contract benefits in effect on the date that services are rendered must be used. Medical Policy, which addresses medical efficacy, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.