**Prior Authorization Review Panel**
**MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

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| **Plan: Keystone First** | **Submission Date**: 11/1/2024 |
| **Policy Number:** ccp.1471 | **Effective Date:** 12/2020<br>**Revision Date:** October 1, 2024 |
| **Policy Name: Robotic orthoses – lower limb** | |

**Type of Submission – Check all that apply:**

- ☐ **New Policy**
- ☒ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

**Please provide any clarifying information for the policy below:**

See tracked changes below.

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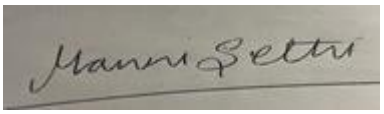
| **Name of Authorized Individual (Please type or print):**<br><br>Manni Sethi, MD, MBA, CHCQM | **Signature of Authorized Individual:**<br><br>  |

# Robotic orthoses – lower limb

Clinical Policy ID: CCP.1471

Recent review date: 10/2024

Next review date: 2/2026

Policy contains: Ekso; exoskeleton; gait disorders; HAL; Honda Walking Assist; Indego; Phoenix; rehabilitation; ReWalk; robotic orthosis; spinal cord injury; stroke.

*Keystone First- CHIP has developed clinical policies to assist with making coverage determinations. Keystone First- CHIP's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First- CHIP, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First- CHIP's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First- CHIP's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First- CHIP will update its clinical policies as necessary. Keystone First- CHIP's clinical policies are not guarantees of payment.*

## Coverage policy

Robotic orthoses (also called robotic exoskeletons) for the lower limb are investigational/not clinically proven and, therefore, not medically necessary for overground ambulation.

Limitations

To ensure user safety, clinicians should follow manufacturer guidelines for inclusion and exclusion criteria that specify body characteristics and other factors that may limit a member's ability to use a robotic orthosis effectively. Other contraindications not consistently described by manufacturers include, but are not limited to (Palermo, 2017):

- Uncontrolled hypotension.
- Poor bone density.
- Unstable spine.
- Unhealed limb or pelvic fractures.
- History of severe neurological injuries other than spinal cord injury.
- Severe concurrent medical diseases: infections, circulatory, heart or lung, and pressure sores.
- Severe spasticity (Modified Ashworth 4).

Alternative covered services

- Physical therapy.
- Non-powered leg braces or single-joint braces.
- Pelvic and thoracic extensions.

- Isocentric bar or cables linking flexion and extension actions of the hip joints.

## Background

Paralysis of the lower limbs following spinal cord injury can result in restrictions in daily upright activity, work capacity, and ambulation ability, and increases the risk of developing secondary medical issues (Gorgey, 2018). Prolonged sitting time is an independent risk factor for cardiovascular disease, cancer, and increased all-cause mortality.

To allow wheelchair users to stand and ambulate after spinal cord injury, leg braces and orthoses, pelvic and thoracic extensions, isocentric bar or cables linking hip joint action, and functional electrical stimulation have been developed (Palermo, 2017). However, all need additional walking aids to sustain ambulation, require high energy demand, and exhibit poor gait patterns that limit their long-term use as an alternative to the wheelchair.

Robotic-based rehabilitation exploits the understanding of neuroplasticity and motor learning to accelerate or promote safe, functional recovery after injury to the central nervous system (Gorgey, 2018). Robotic orthoses (or powered exoskeletons) for the lower limbs are wearable robotic units comprising a system of motors, pneumatics, levers, or hydraulics that are controlled by computer boards to assist the patient in locomotor training.

Robotic orthoses support ambulation by assisting or completely moving the user's legs (Palermo, 2017). The movement can be programmed to mimic a more natural gait pattern than what is achievable with long-leg braces and reciprocating gait orthoses, without the need for tethering. They are becoming lighter and require less energy to operate than standard rigid orthoses. The potential benefits of robotic orthoses may extend beyond the rehabilitation setting to the community setting and afford people lacking leg movement due to neurological injury an additional mobility option.

The U.S. Food and Drug Administration has issued 510(k) approval to several robotic orthoses for the lower torso and limbs to be marketed as Class II devices designated as substantially equivalent to a legally marketed predicate device. They are intended to be used for overground ambulation (as opposed to strictly treadmill use) either in a community setting when accompanied by a specially trained caregiver or in a rehabilitation setting, but not for sports or stair climbing. The indications for each device vary according to neurological injury (i.e., level of spinal cord injury or acquired brain injury) and the coverage area of the device (e.g., torso, hip, knee, or ankle), and each device has specific anatomical and physiological requirements for use. They are (U.S. Food and Drug Administration, 2024):

- Indego® (Parker Hannifin Corp., Macedonia, Ohio) indications:
  - Spinal cord injury at levels T3 to L5 when accompanied by a specially trained caregiver.
  - Spinal cord injury at levels C7 to L5 in rehabilitation institutions.
  - Hemiplegia (with motor function of 4/5 in at least one upper extremity) due to stroke in rehabilitation institutions.
- Ekso® (Ekso Bionics Inc., Richmond, California) indications:
  - Hemiplegia (with motor function of 4/5 in at least one upper extremity) due to traumatic brain injury or stroke in rehabilitation institutions.
  - Spinal cord injury at levels T4 to L5 (with motor function of 4/5 in at least one upper extremity) in rehabilitation institutions.
  - Spinal cord injuries at levels C7 to T3 (American Spinal Injury Association Impairment Scale D with upper extremity motor function of at least 4/5 in both arms) in rehabilitation institutions.
- The Phoenix™ (US Bionics Inc., Emeryville, California) indication: Adults older than age 18 with spinal cord injury at levels T4 to L5 in rehabilitation institutions.

- ReWalk™ (ReWalk Robotics Ltd., Yokneam, Israel) indications:
    - Spinal cord injury at levels T7 to L5 when accompanied by a specially trained caregiver.
    - Spinal cord injury at levels T4 to T6 in rehabilitation institutions.
- ReWalk ReStore™ (ReWalk Robotics Ltd., Yokneam, Israel) indication: Hemiplegia/hemiparesis due to stroke for those who can ambulate at least 1.5 m (5 ft) with no more than minimal to moderate levels of assistance. Designed to assist paretic ankle plantarflexion and dorsiflexion. For use in rehabilitation institutions.
- Honda Walking Assist Device™ (Honda Motor Company Ltd., Alpharetta, Georgia) indication: Patients with gait deficits due to stroke, who exhibit gait speeds of at least 0.4 m/s and are able to walk at least 10 meters with assistance from a maximum of one person. For use in rehabilitation institutions.
- HAL® (hybrid assistive limb) for Medical Use (Lower Limb Type) (Cyberdyne Inc., Tsukuba, Japan) indications for use in rehabilitation institutions:
    - Spinal cord injury at levels C4 to L5 (American Spinal Injury Association Impairment Scale C or D).
    - Spinal cord injury at levels T11 to L5 (American Spinal Injury Association Impairment Scale A with zones of partial preservation, American Spinal Injury Association Impairment Scale B), in patients who exhibit sufficient residual motor and movement-related functions of the hip and knee to trigger and control HAL.
- Atalante X (Wandercraft SAS, Paris, France) for use in rehabilitation institutions for adolescents of 18 years and older and adults able to tolerate a stand-up position with:
    - Hemiplegia due to cerebrovascular accident.
    - Spinal cord injuries at levels T5 to L5.

## Findings

Guidelines

The Department of Veterans Affairs and Department of Defense (2024) guideline found insufficient evidence to recommend for or against the use of robotic devices during gait training. Current evidence from a systematic review and independent experimental studies suggests that while the harms are minimal, there is no significant benefit to non-ambulatory or ambulatory patient populations over standard gait training methods in achieving independent walking or gait velocity gait rehabilitation.

Evidence review

The evidence consisted of small, prospective case series examining the safety and effectiveness primarily of the Indego, Ekso, or ReWalk devices for adult patients with spinal cord injury, and to a lesser extent, HAL, Honda Walking Assist, and Ekso for adults with stroke, in a rehabilitation setting. For spinal cord injury, studies enrolled a majority of middle-aged men with varying levels and severity of injury as indicated by the American Spinal Injury Association Impairment Scale, and varying times since injury. For stroke, the studies generally enrolled participants younger than age 80, with stable cardiovascular conditions and no cognitive deficits, of varying stroke chronicity, and with varying walking ability at baseline.

Robotic orthoses are safe when used with trained supervision and can permit limited upright overground ambulation for users who meet specific device requirements. Adverse events were reported inconsistently, but studies employed safety precautions during training, and recently published studies have improved patient selection criteria to minimize serious adverse events such as falls, fractures, and cardiovascular events.

Training protocols generally involved progressing from familiarity with standing and balancing in the orthosis, to stepping and walking with the device. The proficiency in upright ambulation with respect to gait speed and

distance depended on many factors that were reported inconsistently across studies, making it difficult to determine who would benefit most from these devices. These factors include the level, cause, and chronicity of injury; degree of residual function; and variations in device used, training duration, and goals (e.g., based on participant progress or a fixed time period). Generally, to use these devices, a patient must be able to stand using an assistive device (e.g., standing frame), and their hands and shoulders must be able to support crutches or a walker.

Studies comparing robotic orthoses to other rehabilitative options using the same training protocol are largely absent, so the incremental value of robotic-powered orthoses over less expensive and more widely available supportive orthoses for overground ambulation cannot be determined. The evidence of effectiveness supporting the use of these devices in everyday living environments is anecdotal. Additional research on patients' perspectives, especially satisfaction with an overground robotic orthosis in a locomotor training program or for activities of daily living, is needed.

Spinal cord injury

A systematic review (Lajeunesse, 2016) of seven low-quality studies examined the effectiveness of the ReWalk, Indego, Ekso, and two other robotic orthoses. In general, robotic orthoses are effective for walking in a laboratory, but training protocols lack consistency that would allow identified outcomes to be modified over the term usage. The applicability and effectiveness of lower limb robotic orthoses relative to other mobility and training devices or their use as assistive devices in the community setting has not been demonstrated. The ReWalk has the best results for walking, with a maximum speed of 0.51 meters per second after 45 sessions lasting 60 to 120 minutes; it is comparable to the average speed per day or per week in a manual wheelchair.

A systematic review of 14 studies (Louie, 2015) examined gait speed among non-ambulatory individuals with a thoracic-level, motor-complete injury (American Spinal Injury Association Impairment Scale A or B); one study included ambulatory individuals. Participants presented an average of 5.8 years (standard deviation: 5.6 years) after injury. The review included the ReWalk, Ekso, and Indego devices, and two others developed for research purposes. Training averaged 20 sessions, each of 60 to 100 minutes in duration. For non-ambulatory participants (n = 84), the mean gait speed attained was 0.26 m/s; there was a positive correlation between gait speed and age ($P = .03$), injury level ($P = .03$), and training time ($P = .002$). The authors surmised that the proficiency of powered exoskeletal walking was linked to greater neurological preservation of the spinal cord. Since all powered exoskeletons require an additional gait aid, and some generate stepping in response to lateral shifts of center of mass, an individual with less reliance on the upper extremities for maintaining postural stability will be more able to lift or push their gait aid and to navigate their center of mass.

A systematic review and meta-analysis (Miller, 2016) examined the clinical effectiveness and safety of three robotic orthoses: ReWalk (eight studies); Ekso (three studies); Indego (two studies); and one unspecified device. A total of 111 participants were enrolled with sample sizes ranging from three to 16 patients. Most enrollees were males in their 30s with thoracic-level, complete spinal cord injuries (American Spinal Injury Association Impairment Scale A). Training programs were typically conducted three times per week, 60 to 120 minutes per session, for one to 24 weeks. Ten studies used flat indoor surfaces for training.

After training, 76% of participants were able to ambulate with no physical assistance. The weighted mean distance for the 6-Minute Walk Test was 98 meters. 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 participants, respectively. Earlier studies using first-generation robotic orthoses reported an incidence of fall during training of 4.4%, which resulted in no injury, and a bone fracture incidence of 3.4% during training. In more recent studies, these adverse events were mitigated with improved safety features and patient selection criteria.

Four of the studies (n = 34) using ReWalk, Indego, and Ekso incorporated complex training, including walking outdoors, navigating obstacles, climbing and descending stairs, and performing activities of daily living. No serious adverse events, falls, or fractures were reported, but outcome data were not disaggregated from the other indoor-based studies (Miller, 2016).

Recently published studies provide anecdotal evidence of the feasibility, safety, and satisfaction of patients with spinal cord injury using the ReWalk robotic orthosis. Studies reported improvements in functional walking ability, sitting, standing, and patient satisfaction; adverse events were minor (Guanziroli, 2019; Khan, 2019; Kwon, 2020; Manns, 2019; Muijzer-Witteveen, 2018). Systematic reviews identified a lack of high-quality studies, which prevented drawing firm conclusions on the effects of exoskeletons beyond improvement in walking performance or in comparison with non-robotic options (Stampacchia, 2022; Tamburella, 2022; Zhang, 2022, 2023).

A systematic review of 28 studies (n = 228) reported gait performance using five wearable robotic exoskeletons. The most frequently reported level of spinal cord injury was T6. The amount of robotic training was highly variable across studies. The mean gait speed was 0.31 m/s (standard deviation 0.14 m/s), and the mean distance on the 6-Minute Walking Test was 108.9 meters (±46.7 meters). Fifty-nine percent of patients with cervical level injury were able to ambulate with no upper limb walking aid (crutches or walker). The authors suggested studies comparing multiple robotic devices in the same patients with spinal cord injury to clarify the characteristics and advantages of different wearable robotic exoskeletons (Tan, 2021).

In a pooled analysis of 11 randomized controlled trials, robot-assisted gait training significantly improved lower extremity strength in clinical settings (standardized mean difference = 0.81, 95% confidence interval 0.14 to 1.48; n = 408), but results varied by the type of exoskeleton used and comparator intervention. At least six weeks of training was required to achieve the expected training effect. Robot-assisted gait training significantly improved cardiopulmonary endurance (standardized mean difference = 2.24, 95% confidence interval 0.28 to 4.19; n = 104), but not static pulmonary function measures, which may depend on the extent and level of their injuries, and the robotic training method used (Wan, 2024).

Stroke

A scoping review (Louie, 2016) included seven pre-post clinical studies and four controlled trials, involving 216 participants with sub-acute (< seven weeks) to chronic (> six months) stroke. The devices used were HAL, Honda Walking Assist, and two others. Training periods ranged from single-session to eight-week interventions. Powered robotic exoskeletons can be used safely as a gait training intervention for stroke. With respect to any of the walking outcomes, preliminary findings suggested that exoskeletal gait training was equivalent to traditional therapy for patients with chronic stroke, while meaningful improvement in walking ability with exoskeleton-based gait training was more apparent in sub-acute stroke. Those who were ambulatory at baseline did not appear to benefit from robotic-assisted training. The authors recommended carrying out rigorous, appropriately powered controlled trials before using powered exoskeletons as a clinical tool for post-stroke gait rehabilitation.

A multisite clinical trial (Awad, 2020, Clinicaltrials.gov identifier NCT03499210) examined the safety, reliability, and feasibility of using the ReWalk ReStore model during post-stroke rehabilitation. Thirty-six of the 44 participants with post-stroke hemiparesis completed all five days of ReStore training on the treadmill and overground. Clinician operators reported a low rate of device malfunctions and no device-related falls or serious adverse events. Regardless of their reliance on ancillary assistive devices, participants increased both their device-assisted (change: 0.10 ± 0.03 m/s) and unassisted (change: 0.07 ± 0.03 m/s) maximum walking speeds (both $P < .05$) during rehabilitation.

Two systematic reviews provided results comparing robotic gait training to conventional gait training. A systematic review/meta-analysis of nine studies found robot-assisted gait training after stroke did not increase balance and activities of daily living outcomes more than conventional therapy (Lorusso, 2022). Thirteen studies

(n = 492) of post-stroke patients found (wearable) exoskeleton-assisted training, versus conventional gait training, was superior for walking speed and balance. Those with chronic stroke (> six months) also showed greater overall mobility capacity after exoskeleton-assisted training (Hsu, 2023).

In a pooled analysis of 28 randomized controlled trials (n = 1,251), robot-assisted gait training added to conventional gait training significantly improved short-term lower limb function, gait speed, and activities of daily living over conventional gait training alone, particularly for patients who are within three months from stroke onset or those who are non-ambulatory. There were no significant differences in long-term effects between the two groups. The optimal dosage or robotic device requires further study (Liang, 2024).

A systematic review and meta-analysis of 34 randomized controlled trials (n =1,166) examined the effectiveness of robotic exoskeleton training on lower limb function, activity and participation. Compared to dose-matched conventional rehabilitation, robotic exoskeleton training significantly improved motor control ($P = .009$), gait parameters (Instrumented Gait Velocity, $P = .004$; step length $P = .002$; and cadence, $P = .04$), walking independence ($P = .03$), gait velocity ($P = .001$), balance ($P = .03$), and social participation ($P = 0.01$). Robotic intervention appeared more effective in the early (subacute) phase than in the chronic phase (Yang, 2024).

Other indications

Thirteen studies (n = 68) assessed gait of children with cerebral palsy using a robotic exoskeleton. Studies were limited to small case studies, mixed patients with differing walking conditions at baseline, and sometimes did not allow adequate time to adapt to the exoskeleton (Hunt, 2022).

In participants with cerebral palsy, a systematic review and network meta-analysis (14 studies) found robot-assisted gait training significantly improved lower limb function, balance, and walking endurance but not walking speed or muscle spasticity. Studies of adequate sample size, high-quality, and long-term duration are needed to explore the effects of different devices, dosage, and disease severity on clinical efficacy (Wang, 2023).

In 2021, we added a qualitative synthesis by Tan (2021). No policy changes are required.

In 2022, we added several systematic reviews. No policy changes are required.

In 2023, we added several systematic reviews with no policy changes warranted.

In 2024, we updated the references, reorganized the findings, and added new systematic reviews to the policy with no policy changes warranted.

## References

On September 4, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “orthotic devices” (MeSH), “robotics” (MeSH), "leg" (MeSH), “gait disorders, neurologic/rehabilitation” (MeSH), “spinal cord injuries/rehabilitation” (MeSH), “ReWalk,” “Indego,” “Ekso,” “Honda walking,” “Phoenix,” and “HAL.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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## Policy updates

10/2020: initial review date and clinical policy effective date: 12/2020

10/2021: Policy references updated.

10/2022: Policy references updated.

10/2023: Policy references updated.

10/2024: Policy references updated.