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.

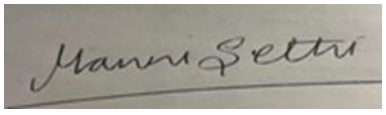
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date:11/1/2025
Policy Number: CCP.1471	Effective Date:12/1/2020 Revision Date:10/1/25
Policy Name: Robotic orthoses – lower limb	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

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

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Keystone First
Family of Health Plans

Robotic orthoses – lower limb

Clinical Policy ID: CCP.1471

Recent review date: 10/2025

Next review date: 2/2027

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

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First'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, 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'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's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First'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 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) clearance 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, 2025):

- 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.
- ReWalk® 7 Personal Exoskeleton (ReWalk Robotics Ltd., Yokneam, Israel) indication:
    - Spinal cord injury at levels T7 to L5 for ambulatory function in home and community settings with supervision.
    - Spinal cord injury at levels T4 to T6 for ambulatory functions in rehab 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, gait velocity, or gait rehabilitation.

According to the American Physical Therapy Association, walking interventions with exoskeletal robotics on a treadmill or elliptical devices should not be performed to improve walking speed and distance in individuals greater than six months following acute-onset central nervous system injury as compared with alternative interventions (evidence quality: I-II; strength of recommendation: strong for stroke and incomplete spinal cord injury). In this population, there appears to be little benefit of robotic-assisted training on walking speed and distance as compared with overground walking training or other interventions (Hornby, 2020).

Evidence review

The evidence for this policy consists of systematic reviews and meta-analyses of randomized controlled trials comparing the safety and effectiveness of robotic-assisted gait rehabilitation alone or as an adjunct to conventional gait training for adults with stroke and spinal cord injury in rehabilitation settings. 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

Systematic reviews of randomized controlled trials comparing robotic exoskeleton and conventional gait training produced mixed results with respect to ground walking ability and functional scores. There is a lack of high-quality studies, which prevented drawing firm conclusions on the effects of exoskeletons beyond short-term improvement in walking performance or in comparison with non-robotic options. The effects of robotic exoskeletons will depend on several factors, including baseline function, the level and degree of injury, the duration of injury, and rehabilitation protocols.

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).

In one analysis of 15 randomized controlled trials (n = 579) of generally low quality, there were no statistically significant improvements between groups in walking speed (10-Meter Walking Test; nine trials, n = 218, $P = .08$), and walking distance (6-Minute Walking Test; six trials, n = 119, $P = .78$). For improving walking speed, robotic and conventional gait training appear equally effective when initiated within six months of injury, but conventional gait training appears to be more effective for those who begin rehabilitation training after six months following injury. Robotic exoskeleton gait training showed a statistically significant improvement over conventional gait training in functional scores such as the Index for Spinal Cord Injury Version II test (eight trials, n = 403, $P = .0001$) and the Lower Extremity Motor Score (11 trials, n = 423, $P = .0005$), and appeared to show superior improvement in walking stability (Timed Up and Go; two trials, n = 28, $P = .04$) and respiratory function (forced expiratory volume in one second; n = 34, $P = .03$), but the statistical power of these calculations was low (Liu, 2025).

In Moriarty's synthesis of 11 randomized controlled trials (n = 552), exoskeleton robotic training produced a statistically significant improvement in walking ability, measured by the Spinal Cord Independence Measure III test (five trials, n = 235, $P < .00001$) and the Walking Index for Spinal Cord Injury II test (eight trials, n = 492, P

< .00001), and walking duration (6-Minute Walk Test; five trials, n = 213, *P* < .00001). Larger scale randomized trials that incorporate secondary outcomes for other organ systems, patient satisfaction, and quality of life, stratified by duration of injury and rehabilitation protocols are needed to corroborate early findings (Moriarty, 2025).

Stroke

Systematic reviews examined multiple randomized trials comparing robot-assisted gait training alone or as an adjunct to conventional gait training. Robotic-assisted rehabilitation may offer short-term benefits to walking function in patients with stroke, but the results are mixed. Authors cited small sample sizes and high heterogeneity in clinical trials contributing to the variation in trial findings.

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; 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).

Hao (2025) analyzed the results of 41 studies (n = 3,279 with hemiplegia). The studies were judged to be of low quality and high heterogeneity. Participants receiving conventional rehabilitation plus robot-assisted therapy improved more in lower limb walking function (Fugl-Meyer scale), balance function (Berg Balance Scale), and the ability to perform activities of daily living (Modified Barthel Index) than those receiving conventional rehabilitation alone (all *P* < .001). When comparing robot-assisted therapy alone to conventional rehabilitation alone, lower limb function (seven trials) and balance function (four trials) scores were higher with robotic therapy (both *P* < .001), but improvements in walking ability (Functional Ambulatory Classification [two trials] and 6-Minute Walk Test [three trials]) and activities of daily living (one trial) were not superior to conventional rehabilitation.

Lee's 2025 systematic review of 23 randomized controlled trials (n = 907) found combined robot-assisted gait training with conventional rehabilitation significantly improved gait function (standard mean difference = 0.51, *P* = 0.001, 17 trials), gait speed (standard mean difference 0.47, *P* = 0.010, 12 trials), gait balance (mean difference 4.58, *P* < 0.001, 10 trials), and activities of daily living performance (standard mean difference = 0.35, *P* = 0.001, 13 trials). In subgroup analyses, end-effector robotic systems generated superior outcomes compared to exoskeletons, particularly for participants in the subacute phase. The most pronounced benefits were seen in gait velocity and dynamic balance, especially with ≤15 training sessions. Most treatment durations were between four and eight weeks, but long-term data are lacking (Lee, 2025).

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 updated the references. 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.

In 2025, we updated the references and deleted several older references with no policy changes warranted.

References

On September 3, 2025, 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.

Department of Veterans Affairs and Department of Defense. VA/DoD clinical practice guideline for the management of stroke rehabilitation. Guideline summary. Version 5.0 2024. Department of Veterans Affairs website. https://www.healthquality.va.gov/guidelines/rehab/stroke/index.asp. Published 2024.

Gorgey AS. Robotic exoskeletons: The current pros and cons. *World J Orthop.* 2018;9(9):112-119. Doi: 10.5312/wjo.v9.i9.112.

Hao QH, Qiu MM, Wang J, Tu Y, Lv ZH, Zhu TM. The effect of lower limb rehabilitation robot on lower limb - motor function in stroke patients: A systematic review and meta-analysis. *Syst Rev*. 2025;14(1):70. Doi: 10.1186/s13643-025-02759-6.

Hornby TG, Reisman DS, Ward IG, et al. Clinical practice guideline to improve locomotor function following chronic stroke, incomplete spinal cord injury, and brain injury. *J Neurol Phys Ther*. 2020;44(1):49-100. Doi: 10.1097/NPT.0000000000000303.

Hunt M, Everaert L, Brown M, Muraru L, Hatzidimitriadou E, Desloovere K. Effectiveness of robotic exoskeleton for improving gait in children with cerebral palsy: A systematic review. *Gait Posture*. 2022;98:343-354. Doi: 10.1016/j.gaitpost.2022.09.082.

Lee JH, Kim G. Effectiveness of robot-assisted gait training in stroke rehabilitation: A systematic review and meta-analysis. *J Clin Med*. 2025;14(13)Doi: 10.3390/jcm14134809.

Liang S, Hong ZQ, Cai Q, et al. Effects of robot-assisted gait training on motor performance of lower limb in poststroke survivors: A systematic review with meta-analysis. *Eur Rev Med Pharmacol Sci*. 2024;28(3):879-898. Doi: 10.26355/eurrev_202402_35325.

Liu S, Chen F, Yin J, Wang G, Yang L. Comparative efficacy of robotic exoskeleton and conventional gait training in patients with spinal cord injury: A meta-analysis of randomized controlled trials. *J Neuroeng Rehab*. 2025;22(1):121. Doi: 10.1186/s12984-025-01649-1.

Moriarty B, Jacob T, Sadlowski M, et al. The use of exoskeleton robotic training on lower extremity function in spinal cord injuries: A systematic review. *J Orthop*. 2025;65:1-7. Doi: 10.1016/j.jor.2024.10.036.

Palermo AE, Maher JL, Baunsgaard CB, Nash MS. Clinician-focused overview of bionic exoskeleton use after spinal cord injury. *Top Spinal Cord Inj Rehabil.* 2017;23(3):234-244. Doi: 10.1310/sci2303-234.

U.S. Food and Drug Administration. 510(k) Premarket Notification database searched using product code PHL. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Last updated September 1, 2025.

Wan C, Huang S, Wang X, et al. Effects of robot-assisted gait training on cardiopulmonary function and lower extremity strength in individuals with spinal cord injury: A systematic review and meta-analysis. *J Spinal Cord Med*. 2024;47(1):6-14. Doi: 10.1080/10790268.2023.2188392.

Wang Y, Zhang P, Li C. Systematic review and network meta-analysis of robot-assisted gait training on lower limb function in patients with cerebral palsy. *Neurol Sci*. 2023;44(11):3863-3875. Doi: 10.1007/s10072-023-06964-w.

Yang J, Zhu Y, Li H, Wang K, Li D, Qi Q. Effect of robotic exoskeleton training on lower limb function, activity and participation in stroke patients: A systematic review and meta-analysis of randomized controlled trials. *Front Neurol*. 2024;15:1453781. Doi: 10.3389/fneur.2024.1453781.

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.

10/2025: Policy references updated.