Molina Clinical Policy
Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities: MEDICARE
Policy No. 244b

Last Approval: 10/21/2026
Next Review Due By: October 2027

DISCLAIMER

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

OVERVIEW

An exoskeleton is an external structure with joints and linkages that can be thought of as wearable robots constructed around the shape and function of the human body. A powered exoskeleton, as defined in this policy, is an exoskeleton-like framework worn by a human that contains a power source that provides energy for limb movement. **Robotic lower body exoskeletons** are designed to enable individuals with lost lower limb function to perform ambulatory functions, such as standing upright and walking. Depending on the system, the device may consist of an upper-body harness or trunk, lower-limb braces, motorized joints, sensors, and a computerized controller powered by a rechargeable battery. Some devices use a wrist-worn wireless remote control to command the device to stand, sit, or walk. The user may be secured to the device at the waist, along the lower extremities, and at the feet. Depending on the device, crutches, a walker, or other support systems may be used to maintain stability. These devices have been developed to aid both ambulation and rehabilitation for individuals with conditions such as spinal cord injuries, stroke, traumatic brain injury and other disorders affecting mobility.

Regulatory Status

The United States Food and Drug Administration (FDA) has cleared several robotic lower body exoskeleton devices via the 510(k) pathway under product code PHL, such as the ReWalk, Ekso, Ekso GT, Indego, and ExoAtlet-II systems. FDA-cleared indications vary by device, and include spinal cord injury (SCI), multiple sclerosis, stroke, or other neurologic conditions. Depending on the device, use may require supervision by a trained caregiver or healthcare professional.

In 2014, ReWalk received FDA De Novo classification (DEN130034), which established a new classification for powered exoskeletons and allowed new substantially equivalent devices to be cleared through the 510(k) premarket notification process. The current ReWalk 7 Personal Exoskeleton (K241822) device fits over the lower limbs and part of the upper body and is intended to enable individuals with SCI at levels T7 to L5 to perform ambulatory functions in home and community settings with the supervision of a specially certified companion. The device is also indicated for individuals with SCI at levels T4 to T6 to perform ambulatory functions in rehabilitation institutions. ReWalk ReStore (K190337) is a portable, lightweight exo-suit that was cleared in 2019 for assisting ambulatory function during rehabilitation in people with stroke-related hemiplegia/hemiparesis.

Ekso and Esko GT (K143690) were FDA-cleared in 2016. The current EksoNR (K220988) was FDA-cleared in 2022 and is intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for individuals with multiple sclerosis, acquired brain injury (including traumatic brain injury and stroke) and SCIs at levels T4 to L5 and C7 to T3.

ExoAtlet-II (K201473) received FDA clearance in 2021 for use under the supervision of a trained physical therapist in rehabilitation clinics to perform ambulatory functions for patients with SCI at levels T4 to L5 or C7 to T3.

Indego (K152416) received FDA clearance in 2016. Its current indications are approved for individuals with SCI at levels T3 to L5, and C7 to L5 in rehabilitation institutions, and patients with hemiplegia due to stroke.

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HAL for Medical Use (Lower Limb Type) (K171909) was FDA-cleared in 2018 under product codes PHL and HCC. The HAL is intended for use by patients with SCI at levels C4 to L5 and T11 to L5.

While not an exhaustive list, other notable FDA-cleared devices include the Keeogo (K201539), Phoenix Suit X (K183152), GEMS-H (K213452), Atalante X (K250904), Eve (K260381), and Trexo Theo (K254198) systems.

COVERAGE POLICY

Powered or robotic lower body exoskeleton devices (e.g., ReWalk, Ekso, Indego, ExoAtlet-II, HAL, Keeogo, Phoenix Suit X, etc.) are considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

All prior authorization requests for covered benefits are reviewed for medical necessity on an individual basis.

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

SUMMARY OF MEDICAL EVIDENCE

Randomized Controlled Trials

Chang et al. (2026) conducted a multicenter, single-blind RCT to evaluate robot-assisted gait training (RAGT) using the ANGEL LEGS M20 torque-assisted exoskeleton in adults with early subacute ischemic or hemorrhagic stroke. A total of 151 participants were randomized at a 1:1 ratio to either RAGT (n = 74) or conventional gait training (n = 77) and a total of 127 participants completed the full 4-week intervention. Study participants had severe ambulatory impairment at baseline (Functional Ambulatory Category [FAC] score 0 or 1) with relatively preserved trunk control, as measured with the Trunk Control Test ($\geq$ 50), and were 7 to 90 days post stroke. Both groups received 60 minutes of gait rehabilitation 5 days a week for 4 weeks. RAGT participants received 30 minutes of conventional training plus 30 minutes of exoskeleton-assisted training while control participants received 60 minutes of conventional training. The primary outcome was change in ambulatory function measured by FAC from baseline to post 4-week intervention. FAC improved significantly in both groups, with a median change of 3.0 points for RAGT and 2.5 for controls; however, the between-group difference was not significant after adjusting for the lower baseline FAC score in the RAGT group ($p = 0.395$). Other outcomes included independent gait, defined as walking > 10 meters without assistance and a corresponding FAC of > 3, which was achieved in 77.6% of RAGT participants and 75.4% of controls ($p = 0.769$), and the difference between groups was not statistically significant ($p = 0.769$). There were no significant differences between balance, lower-extremity motor function, depression, or quality of life. Lower limb strength, measured by the Motricity Index, improved significantly more with RAGT participants than controls, with a mean change of 15.9 $\pm$ 14.2 versus 11.1 $\pm$ 11.2 points ($p = 0.034$). No significant adverse events were observed in either group. Four RAGT participants developed new major medical conditions, such as stroke recurrence, but clinical review determined the events were unrelated to the intervention. The authors concluded that 4 weeks of gait training with RAGT was not superior to conventional gait rehabilitation for improving ambulatory function in patients with subacute stroke.

Zenesini et al. (2026) conducted a multicenter, single-blind RCT to evaluate whether adding RAGT to conventional rehabilitation, using the Ekso-GT device, improves walking outcomes in adults with chronic, motor-incomplete spinal cord injury (SCI). Thirty-six participants with grades C or D SCI, using the American Spinal Injury Association (ASIA) Impairment Scale, were randomized to either conventional rehabilitation alone (n = 16) or conventional rehabilitation + Ekso-GT training (n = 20) for 8 weeks. RAGT consisted of 30-40 minutes of active walking 3 times weekly for 12 sessions during the first 4 weeks. The primary outcome was the proportion of patients achieving $\geq$ 10% improvement from baseline in walking speed using the 10-Meter Walk Test (10-MWT) at 4 weeks, with responder rates of 33.3% for RAGT participants and 46.7% for control group participants, with no significant difference between groups ($p = 0.44$). Secondary outcomes included 10-MWT at 8 weeks, with responder rates of 43.8% for RAGT participants and 66.7%

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for control group participants (p = 0.20). Adjusted logistic regression showed no significant benefit with RAGT at eith 4 weeks (odds ratio [OR] 0.54, 95% confidence interval [CI] 0.13-2.30, p = 0.40) or 8 weeks (OR 0.33, 95% CI 0.07-1.53, p = 0.16). 6-Minute Walk Test (6-MWT) increased by 42.6 meters at 8 weeks across the study cohort (95% CI 14.3-70.9, p = 0.003) without significant between-group differences at either 4 or 8 weeks. The authors concluded that RAGT using the Ekso-GT device is safe and feasible but did not demonstrate superior efficacy over conventional rehabilitation and yielded no additional function benefits under the tested conditions.

Spungen et al. (2024) conducted a multi-center randomized clinical trial Across 15 VA medical centers involving 161 veterans with chronic SCI. Participants were randomized 1:1 to either standard of care SOC wheelchair use (n=83) or SOC plus at will use of the FDA cleared ReWalk exoskeletal assisted walking (EAW) device (n = 78) over 4 months in home and community settings all participants were included in the intent-to-treat analysis while a secondary per protocol analysis included 102 study completers (SOC: n=45; EAW n=57). Primary outcomes included the proportion of participants achieving a ≥4-point improvement in the mental component summary score of the Veterans RAND 36 Item Health Survey (MCS/VR-36) and a ≥10% improvement in the total T score of the Spinal Cord Injury-Quality of Life (SCI-QOL) physical and mental domain (bladder, bowel and pain). The secondary outcome was a reduction of ≥1.0kg in total body far mass (TBFmass). Following randomization, outcome data was collected at the initial baseline, and then at three further time points: after the orientation and training phase, at 2 months, and at 4 months, which represented the primary outcome collection point. No statistically significant differences were observed between groups for either primary outcome (MCS/VR-36: p=.80; SCI-QOL: p=0.93 or for TBFmass loss (p=0.83). Exploratory endpoints including sleep disturbance, emotional health, social participation, bowel function, metabolic indices and functional indices also showed no significant between group differences. Device usage in the EAW group varied widely, with participants averaging 86 minutes per week (SD=46) over 7.7 weeks (SD_5.3), with monthly step counts ranging from 250 to 57,766, with a mean distance of 1.53 miles. Reported barriers to use included lack of a companion, illness, scheduling conflicts, travel, and inclement weather. Adverse events were similar between groups: the EAW group experienced 18 serious adverse events (SAEs) and 157 total events, while the SOC group reported 28 SAE's and 165 total events. SAE's occurred in 15.4% of EAW participants and 16.9% of SOC participants. Eleven fractures were reported, including two calcaneal fractures attributed to device use during initial standing and stepping; both were non-traumatic and possibly pre-existing. The authors concluded that ReWalk use in home and community settings did not yield clinically meaningful improvements in mental, physical, or medical health outcomes compared to wheelchair use alone. Limitations included lack of blinding, use of convenience sample, absence of a control group for device usage, and substantial attrition in both arms, which may have introduced bias and limited interpretability.

Yoo et al. (2023) conducted a randomized controlled pilot trial that assessed the effectiveness of overground RAGT in stroke patients. Seventeen patients were divided into an intervention group (n = 9) and a control group (n = 8). Both groups underwent conventional neurorehabilitation, but the intervention group also received 30 minutes of RAGT using a robotic exoskeleton (ExoAtlet Medy). Participants were stroke patients over 18 years old in the subacute stage (≤6 months), unable to walk independently, and able to sit and follow instructions. Exclusion criteria included severe lower limb spasticity or contracture and cardiovascular issues. The primary outcome measured was the functional ambulatory category (FAC), with secondary outcomes including the Berg Balance Scale, EQ-5D, timed-up-and-go, and 10-m walk test. Both groups showed significant improvement in the Berg Balance Scale and EQ-5D scores ($P < .05$). However, only the RAGT group showed significant improvement in FAC, timed-up-and-go, and 10-m walk test scores ($P < .05$). The intervention group also had greater improvement in FAC and EQ-5D compared to the control group ($P < .05$). Limitations of the study included small sample size, differing dropout rates, and variance in the time since stroke onset between groups.

Systematic Reviews and Meta-Analyses
Zhang et al. (2026) conducted a systematic review and meta-analysis to evaluate lower limb RAGT compared with conventional rehabilitation or non-robotic gait training in adults with stoke. The review included 11 RCTs for a total of 532 participants with ischemic or hemorrhagic stroke accompanied with lower-limb motor dysfunction, walking impairment, or hemiparetic gait. Time since stroke varied from 0.6 to 189.6 months. Devices included independently wearable exoskeletons and mobile frame and platform-coupled exoskeleton-type systems. RAGT interventions lasted 15 days to 6 weeks. Outcomes included spatial gait and temporal gait asymmetry, and gait speed, with no standardized test used across studies. RAGT significantly reduced spatial gait asymmetry compared with control treatment (standard mean difference (SMD – 0.68, 95% CI – 1.13 to -0.22, $p < 0.01$), although heterogeneity was moderated ($I^2 = 57.43\%$). Temporal gait asymmetry was not significantly different between groups (SMD -0.85, 95% CI -1.90 to 0.20,

p = 0.11), with substantial heterogeneity (I^2 = 91.09%). Gait speed was significantly higher after RAGT compared to controls (SMD 0.46, 95% CI 0.12 to 0.81, p = 0.01), with moderate heterogeneity (I^2 = 68.66%); however, since gait-speed measures and units varied substantially, results could not be used to determine whether a clinically important gait-speed threshold was achieved. Risk of bias included concerns with missing outcome data, selection of reported results, outcome measurements, and deviations from intended interventions. The authors highlighted heterogeneity in stroke stage, baseline walking ability, device design, training dose and environment, and control interventions. GRADE certainty was rated very low for outcomes. Adverse events were reported inconsistently across studies and the authors stated that the available evidence did not permit a definitive judgment regarding safety. The authors concluded that lower-limb RAGT may reduce spatial gait asymmetry and improve gait speed after stroke, while its effect on temporal gait asymmetry remains uncertain.

Zhang et al. (2023) evaluated walking efficiency in SCI patients utilizing a lower limb exoskeleton compared to mechanical gait orthosis. Researchers extracted data to complete a systematic review of walking efficiency comparing a powered exoskeleton and non-powered mechanical gait orthosis. They found that data synthesis using meta-analysis was not possible due to inconsistencies in study design, methodologies, and outcome measurements. Review of 11 trials representing 14 different orthotics were evaluated, but only general information was obtained. Overall walking efficiency in SCI patients was more effective on improving gait performance when using a powered lower limb exoskeleton, but evidence was limited. Meaningful conclusions were unable to be reached due to the need for more high-quality studies comparing larger groups of patients for longer periods of time. While researchers have identified the complications SCI patients develop due to sedentary lifestyles, it is not clear how robotic exoskeletons will impact future treatment. Randomized control trials are needed to determine when and how robotic exoskeletons can improve treatment for patients with SCI.

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

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

National and Specialty Organizations

The U.S. **Department of Veterans Affairs (VA)** and **Department of Defense (DoD)** (2024) published the *VA/DoD Clinical Practice Guideline for the Management of Stroke Rehabilitation*. The guideline states: “There is insufficient evidence to recommend for or against robot-assisted therapy to improve upper or lower extremity motor outcomes.”

The **American Physical Therapy Association (APTA)** and **Academy of Neurologic Physical Therapy (ANPT)** published a *Clinical Practice Guideline to Improve Locomotor Function Following Chronic Stroke, Incomplete SCI, and Brain Injury* (Hornby et al. 2020). The guidelines discourage the use of powered exoskeletons on a treadmill or elliptical to improve walking speed or distance following an acute-onset central nervous system injury in patients who are more than six months post-injury due to minimal benefit, increased costs, and increased time (level I to II evidence, strong recommendation). However, the authors noted that this recommendation may not apply to non-ambulatory individuals or those who require robotic assistance to ambulate.

The **American Heart Association (AHA)** and the **American Stroke Association (ASA)** published a *2026 Guideline for Adult Stroke Rehabilitation and Recovery* (Richards et al. 2026). The guidelines states that for ambulatory patients with stroke, RAGT is not recommended over task-specific overground gait training to improve walking and mobility (Class 3: No Benefit, Level of Evidence A). RAGT involves the use of devices such as exoskeletons, end-effector systems, or treadmill-based platforms to support and guide lower limb movement during walking practice. However, in ambulatory stroke patients, RAGT has shown similar outcomes compared with conventional gait training. “Despite the technological sophistication, the high cost of robotic devices and the time required for setup may limit their practicality in routine clinical settings.” Evidence remains limited for RAGT use in non-ambulatory patients or in protocols using end-effector systems remains. Further research is needed to determine the cost effectiveness and clinical benefit.

SUPPLEMENTAL INFORMATION

American Spinal Cord Injury Association (ASIA) Impairment Scale: A universal classification tool for spinal cord injury (SCI) based on a standardized sensory and motor assessment, with the most recent revision published in 2026. The ASIA Impairment Scale (AIS) is a component of the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) (ASIA 2026).

CODING & BILLING INFORMATION

HCPCS (Healthcare Common Procedure Coding System)

Code	Description
K1007	Bilateral hip, knee, ankle, foot (HKAFO) 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]

CODING DISCLAIMER: Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/21/2026	Policy revised. Title changed to “Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities.” Added “All prior authorization requests for covered benefits are reviewed for medical necessity on an individual basis." to coverage section.
10/08/2025	Policy reviewed. No changes to coverage criteria.
10/09/2024	Policy reviewed. No changes to coverage criteria.
10/12/2023	Policy reviewed. No changes to coverage criteria.
10/12/2022	Policy revised, scope of policy expanded, and title updated from ‘Lower-Limb Robotic Exoskeleton (ReWalk- Personal) for Paraplegia in Spinal Cord Injury’ to ‘Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities (ReWalk).’ IRO Peer Review by practicing, board-certified physician with a specialty in Pain Management and Physical Medicine and Rehabilitation. Policy revisions expanded to include paraplegia in patients with lower-limb disabilities. Updated Summary of

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	Medical Evidence. Clinical practice guidelines added.
10/13/2021	Policy reviewed. No changes to coverage criteria.
09/16/2020	Policy reviewed. No changes to coverage criteria.
09/18/2019	Policy reviewed. No changes to coverage criteria.
03/08/2018	Policy reviewed. No changes to coverage criteria. IRO Peer Review on February 1, 2018, by practicing, board-certified physician with a specialty in Pain Management and Physical Medicine and Rehabilitation.
06/22/2017	Policy reviewed. No changes to coverage criteria.
12/14/2016	Policy reviewed. No changes to coverage criteria.
12/16/2015	Policy reviewed. No changes to coverage criteria.
08/05/2015	New policy.

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