1.03.04	Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities		
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Section:	1.0 Durable Medical Equipment	**Page:**	Page 1 of 17

Policy Statement

I. Use of a powered exoskeleton for ambulation in individuals with lower-limb disabilities is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

See the Codes table for details.

Description

The goal of the powered exoskeleton is to enable people who do not have volitional movement of their lower extremities to be able to fully bear weight while standing, to walk, and to navigate stairs. The devices have the potential to restore mobility
and,
thus, might improve functional status, quality of life, and health status for patients with spinal cord injury, multiple sclerosis, amyotrophic lateral sclerosis, Guillain-Barré syndrome, and spina bifida.

Related Policies

- Functional Neuromuscular Electrical Stimulation
- Microprocessor-Controlled Prostheses for the Lower Limb

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 2014, ReWalk (ReWalk Robotics, previously Argo Medical Technologies) was granted a de novo 510(k) classification (K131798) by the U.S. Food and Drug Administration (FDA) (Class II; FDA product code: PHL). The new classification applies to this device and substantially equivalent devices of this generic type. ReWalk (current version ReWalk Personal 6.0) is the first external, powered, motorized orthosis (powered exoskeleton) used for medical purposes that is placed over a person's paralyzed or

weakened limbs for the purpose of providing ambulation. De novo classification allows novel products with moderate- or low-risk profiles and without predicates that would ordinarily require premarket approval as a Class III device to be down-classified in an expedited manner and brought to market with a special control as a Class II device.

The ReWalk is intended to enable individuals with spinal cord injury at levels T7 to L5 to perform ambulatory functions with supervision of a specially trained companion in accordance with the user assessment and training certification program. The device is also intended to enable individuals with spinal cord injury at levels T4 to T6 to perform ambulatory functions in rehabilitation institutions in accordance with the user assessment and training certification program. The ReWalk is not intended for sports or stair climbing.
Candidates for the device should have the following characteristics:

- Hands and shoulders can support crutches or a walker,
- Healthy bone density,
- Skeleton does not suffer from any fractures,
- Able to stand using a device such as a standing frame,
- In general good health,
- Height is between 160 cm and 190 cm (5'3" to 6'2"), and
- Weight does not exceed 100 kg (220 lb).

In 2019, the ReWalk ReStore™, a lightweight, wearable, exo-suit, was approved for rehabilitation of individuals with lower-limb disabilities due to stroke.

In 2016, Indego (Parker Hannifin) was cleared for marketing by the FDA through the 510(k) process (K152416). The FDA determined that this device was substantially equivalent to existing devices, citing ReWalk as a predicate device. Indego is "intended to enable individuals with spinal cord injury at levels T7 to L5 to perform ambulatory functions with supervision of a specially trained companion." Indego has also received marketing clearance for use in rehabilitation institutions.

In 2016, Ekso™ and Ekso GT™ (Ekso Bionics® Inc) were cleared for marketing by the FDA through the 510(k) process (K143690). The ReWalk was the predicate device. Ekso is intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for the following populations with upper extremity motor function of at least 4/5 in both arms: individuals with hemiplegia due to stroke, individuals with spinal cord injuries at levels T4 to L5, and individuals with spinal cord injuries at levels of C7 to T3.

In 2017, Hybrid Assistive Limb (HAL™) for Medical Use (Lower Limb Type) (CYBERDYNE Inc.) was cleared for marketing by the FDA through the 510(k) process (K171909). The ReWalk was the predicate device. The HAL is intended to be used inside medical facilities while under trained medical supervision for individuals with spinal cord injury at levels C4 to L5 (American Spinal Injury Association [ASIA] Impairment Scale C, ASIA D) and T11 to L5 (ASIA A with Zones of Partial Preservation, ASIA B)
In 2020, Keeogo™ (B-Temia) exoskeleton was cleared for marketing by the FDA through the 510(k) process (K201539). The Honda® Walking Assist Device was the predicate device. Keeogo is intended for use in patients with stroke in rehabilitation settings.

In 2021, ExoAtlet-II® (ExoAtlet Asia Co. Ltd.) was cleared for marketing by the FDA through the 510(k) process (K201473). The Ekso/Ekso GT was the predicate device. ExoAtlet-II is intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for the following populations with upper extremity motor function of at least 4/5 in both arms: individuals with spinal cord injuries at levels T4 to L5, and individuals with spinal cord injuries at levels of C7 to T3 (ASIA D).

In 2022, GEMS-H® (Samsung Electronics Co. Ltd.) was cleared for marketing by the FDA through the 510(k) process (K213452). The Honda Walking Assist Device was the predicate device. GEMS-H is intended to help assist ambulatory function in rehabilitation institutions under the supervision of a trained healthcare professional for individuals with stroke who have gait deficits and 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 1 person.

In 2022, EksoNR™ (Ekso Bionics Inc) was cleared for marketing by the FDA through the 510(k) process (K220988). EksoNR is intended to perform ambulatory functions in rehabilitation institutions under the supervision of a trained physical therapist for the following populations: individuals with multiple sclerosis (upper extremity motor function of at least 4/5 in at least 1 arm); individuals with acquired brain injury, including traumatic brain injury and stroke (upper extremity motor function of at least 4/5 in at least 1 arm); individuals with spinal cord injuries at levels T4 to L5 (upper extremity motor function of at least 4/5 in both arms), and individuals with spinal cord injuries at levels of C7 to T3 (ASIA D with upper extremity motor function of at least 4/5 in both arms).

In 2022, Atalante® (Wandercraft SAS) was cleared for marketing by the FDA through the 510(k) process (K221859). The Indego was the predicate device. Atalante is intended to enable individuals (>18 years of age, able to tolerate a stand-up position) with hemiplegia due to cerebrovascular accident to perform ambulatory functions and mobility exercises, hands-free, in rehabilitation institutions under the supervision of a trained operator. The Atalante X® was cleared for marketing by the FDA through the 510(k) process (K232077) and is intended to perform ambulatory functions and mobility exercises, hands-free, in rehabilitation institutions for individuals with hemiplegia due to cerebrovascular accident and individuals with spinal cord injuries at levels T5 to L5.
FDA product code: PHL.

Rationale

Background

An exoskeleton is an external structure with joints and links that might be regarded as wearable robots designed around the shape and function of the human body. A powered exoskeleton, as described in this evidence review, consists of an exoskeleton-like framework worn by a person that includes a power source supplying energy for limb movement.

One type of powered lower-limb exoskeleton (e.g., ReWalk™, Indego®) provides user-initiated mobility based on postural information. Standing, walking, sitting, and stair up/down modes are determined by a mode selector on a wristband. ReWalk includes an array of sensors and proprietary algorithms that analyze body movements (e.g., tilt of the torso) and manipulate the motorized leg braces. The tilt sensor is used to signal the onboard computer when to take the next step. Patients using the powered exoskeleton must be able to use their hands and shoulders with forearm crutches or a walker to maintain balance. Instructions for ambulating with ReWalk[1,] are to place the crutches ahead of the body, and then bend the elbows slightly, shifting weight toward the front leg, leaning toward the front leg side. The rear leg will lift slightly off of the ground and then begin to move forward. Using the crutches to straighten up will enable the rear leg to continue moving forward. The process is repeated with the other leg.

To move from a seated to standing position or vice versa, the desired movement is selected by the mode selector on the wrist. There is a 5-second delay to allow the individual to shift weight (forward for sit-to-stand and slightly backward for stand-to-sit) and to place their crutches in the correct position. If the user is not in an appropriate position, a safety mechanism will be triggered. Walking can only be enabled while standing, and the weight shift must be sufficient to move the tilt sensor and offload the back leg to allow it to swing forward. Continuous ambulation is accomplished by uninterrupted shifting onto the contralateral leg. The device can be switched to standing either via

the mode selector or by not shifting weight laterally for 2 seconds, which triggers the safety mechanism to stop walking. Some patients have become proficient with ReWalk by the third week of training.[2,]

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Pre-post study designs (using patients as their own controls) are most likely to provide evidence on the effects of a powered exoskeleton on health outcomes. Outcomes of interest are the safety of the device, the effect of the exoskeleton on the ability to ambulate, and the downstream effect of ambulation on other health outcomes (e.g., bowel and bladder function, spasticity, cardiovascular health). Of importance in this severely disabled population is the impact of this technology on activities of daily living, which can promote independence and improved quality of life.
Issues that need to be assessed include the device's performance over the longer-term when walking compared with wheelchair mobility, the user's usual locomotion outside of the laboratory setting, and the use of different exoskeletons or the training context.[3,] Adverse events (e.g., falling, tripping) can impact both safety and psychological security and also need to be assessed.

Powered Exoskeleton for Ambulation

Clinical Context and Therapy Purpose

The purpose of a powered exoskeleton for ambulation is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with lower-limb disabilities. The goal of the powered exoskeleton is to enable individuals who do not have volitional movement of their lower extremities to bear weight fully while standing, to ambulate over ground, and to ascend and descend stairs.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with spinal cord injury, multiple sclerosis, amyotrophic lateral sclerosis, Guillain-Barré syndrome, and spina bifida.

Interventions
The therapy being considered is powered exoskeleton systems that use posture control and are being evaluated for home use:

- The EksoGT robotic exoskeleton (now updated to EksoNR ; Ekso Bionics) is available institutionally for rehabilitation. It is undergoing testing for personal use for ambulation in several registered trials.
- The Indego powered exoskeleton (also known as the Vanderbilt exoskeleton; Parker Hannifin) is used for gait training and is now available for home use. It includes functional electrical stimulation and weighs 29 pounds.
- ReWalk Personal 6.0 (ReWalk Robotics) consists of an onboard computer, sensor array, and rechargeable batteries that power the exoskeleton, which are contained in a backpack.
- The X1 Mina® Exoskeleton is a joint project of the National Aeronautics and Space Administration (NASA) Johnson Space Center and the Florida Institute for Human and Machine Cognition. It was developed to provide mobility for both abled and disabled users, for rehabilitation, and exercise. It weighs 26 kg (57 lb).
- Keeogo (B-Temia) exoskeleton is intended for patients with stroke in rehabilitation settings. It has been studied for personal use in the outpatient setting.

Powered exoskeleton systems that use joystick control and are being evaluated for home use include:

- REX® (REX Bionics) is designed for clinical use in rehabilitation centers and hospitals. REX® P is designed for personal use and does not require use of crutches or a walker for stability, leaving the user hands-free.
- WPAL® (Wearable Power-Assist Locomotor; Fujita Health University) is designed for use with a custom walker.
- HAL (Hybrid Assistive Limb).
- Phoenix® (SuitX).

Comparators
The following practice is currently being used to treat lower-limb disabilities: standard rehabilitation and/or assistive devices without a powered exoskeleton.

Outcomes
The general outcomes of interest are restoration of mobility, increased function, and improved health status and quality of life for wheelchair-bound patients. Some of the potential secondary health benefits associated with increased mobility include strength and cardiovascular health, decreased spasticity, improved bladder and bowel function, and psychosocial health.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

There is limited information about the use of powered exoskeletons outside of the institutional setting. Standard measures of walking function include the Timed Up-and-Go test, which assesses the time required to get up from a chair and commence walking; the 10-meter walk test, which evaluates the time required to walk 10 meters; and the 6-minute walk test, which measures the distance walked in 6 minutes. A less used test, the timed stair test, evaluates the time it takes to ascend or descend 10 stairs and has been used in powered exoskeleton studies.

Systematic Review

A systematic review by Tamburella et al (2022) qualitatively summarized the effects of the powered exoskeleton (Ekso, ReWalk, Indego, REX, or HAL) on walking and on secondary health outcomes in patients with spinal cord injury.[4,] A total of 41 studies (566 patients) were included, of which only 1 was an RCT (Table 1). The characteristics of the systematic review are summarized in Table 2. The average patient age was 43.58 ± 7.84 years. The study assessed the effects of the powered exoskeleton on 14 domains: walking, cardiorespiratory/metabolic responses, spasticity, balance, quality of life, human-robot interaction, robot data, bowel functionality, strength, activities of daily living, neurophysiology, sensory function, bladder functionality, and body composition/bone density. The effects of Ekso, ReWalk, Indego, REX, and HAL were analyzed in 20, 14, 4, 2, and 1 studies, respectively. Of the 41 studies, 13 reported different adverse events during training with Ekso (n=5 studies), ReWalk (n=5), Indego (n=2), and HAL (n=1). The most frequent adverse events were skin lesions, while the less frequent adverse events were extreme fatigue, falls, bone fractures, or muscle strain. The average total number of sessions across the studies ranged from 1 to 55, and 42% of studies performed 3 sessions per week. Only 2 studies (both on Ekso) compared powered exoskeleton with other interventions (ie, conventional physical therapy). In the studies that reported follow-up, follow-up examinations were performed 4 weeks after the end of treatment (n=3); or after 2 months (n=1), 2 to 3 months (n=1), and 12 to 15 months (n=1). Table 3 summarizes the results of the systematic review. Most studies used outcome measures relating to the walking domain; walking velocity was measured per the 10-meter walking test in 18 studies and the 6-minute walk test in 13 studies. For each domain, the systematic review reported the data as "significant" if the authors of each included study reported significant changes in their published data. A major limitation of the systematic review was that all included studies were of moderate or low methodological quality level, mainly due to poor study design. Other limitations included the small, heterogeneous number of participants; variable dosage of interventions; the absence of control groups and/or follow-up assessments in many studies; and the various parameters adopted in each domain for different types of comparisons. The heterogeneity of outcome measures precluded the ability to make general conclusions on the effects of powered exoskeletons.

Table 1. Studies Included in the Systematic Review

Study	Tamburella et al (2022)[4,]
Chun et al (2020)[5,]	

Study	Tamburella et al (2022)[4],
Gagnon et al (2018)[21],	

Study	% of Studies Addressing Each Domain	% of Studies with ≥1 Outcome Measure for Each Domain with Significant Improvements After Powered Exoskeleton Training
Neurophysiology	4	3.8
Body composition and body density	1	3.8
Bowel functionality	8	2.3
Sensory function	2	0
Bladder function	2	0

ADL: activities of daily living; QOL: quality of life.

Randomized Controlled Trial

An RCT (The Veterans Health Administration Cooperative Studies Program: Powered Exoskeletons for Persons with Spinal Cord Injury [PEPSCI] Trial) was designed for the study of exoskeletal-assisted walking in the home and community environments in patients with chronic spinal cord injury.[44,] Of 424 enrolled patients, 263 failed screening and were not randomized. Of the 161 randomized patients, 151 (93.8%) were male; the mean age (standard deviation) was 46.2 (13.4) years. The intervention group consisted of standard of care (wheelchair for mobility) and use of ReWalk 6.0 exoskeleton at home for 4 months, while the control group consisted of standard of care (wheelchair) only. The primary aims of the study were to demonstrate clinically meaningful net improvements in the Mental Component Summary of the Veterans Rand-36 (MCS/VR-36) and in patient-reported outcomes for the Spinal Cord Injury Quality of Life (SCI-QOL) assessment tool for the physical-medical health domain components of bladder, bowel, and pain item banks. The major secondary aim was to demonstrate a reduction in total body fat mass. Tables 4 and 5 provide a summary of the characteristics and results of the study. Study results have not been published and were obtained from ClinicalTrials.gov (see NCT02658656 in Table 9; Ongoing Clinical Trials section). Limitations of the RCT include extensive exclusion criteria (resulting in several patients failing the screening process); furthermore, the use of an exoskeleton as an intervention prevented the ability for single- or double-blinding.

Table 4. Summary of Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions (N=161)	
					Active (n=78)	Comparator (n=83)
Spungen et al (2020)[44]; NCT02658656	US	15	2016-2021	• Veterans or active duty military personnel ≥18 years of age • With traumatic or non-traumatic SCI of 6 months duration • Using a wheelchair for indoor and outdoor mobility	ReWalk Personal 6.0 exoskeleton (in-home use for 4 months) + wheelchair	Wheelchair only

NCT: national clinical trial; SCI: spinal cord injury.

Table 5. Summary of Randomized Controlled Trial Results

Study	No. (%) of Patients with ≥4-Point Change on the MSC/VR-36 from Baseline to 4 Months Post Intervention[1]	No. (%) of Patients with ≥10% Decrease on the SCI-QOL PMH Domain from Baseline to 4 Months Post Intervention[2]	No. (%) of Patients with ≥1 kg of Total Body Fat Loss from Baseline to 4 Months Post Intervention[3]	No. (%) of Patients with Serious Adverse Events
Spungen et al (2020)[44]; NCT02658656				
ReWalk Personal 6.0 + wheelchair	12 (15.4)	10 (12.8)	14 (17.9)	11 (14.1)
Wheelchair	14 (16.9)	11 (13.3)	16 (19.3)	16 (16.87)
RR	0.91	0.97	0.93	
95% CI	0.45 to 1.85	0.44 to 2.15	0.49 to 1.79	
p-value	.798	.935	.829	

[1]Possible range of the MCS/VR-36 is 0 to 100, with a higher score indicating higher mental well-being.
[2]The PMH score is a sum of the SCI-QOL scores from the Bladder Management Difficulties, Bowel Management Difficulties, and Pain Interference item banks; possible range of the PMH score is 110 to 253, with a lower score indicating better physical medical well-being.
[3]Measured by dual photon x-ray absorptiometry (DXA) scan.
CI: confidence interval; MCS/VR-36: Mental Health Component Summary of the Veterans Rand-36; NCT: national clinical trial; PMH: Physical Medical Health; RR: risk ratio; SCI-QOL: Spinal Cord Injury Quality of Life.

Randomized Crossover Trial

One small (N=29), randomized, open-label, cross-over study evaluated the Keeogo exoskeleton for patients with multiple sclerosis.[45,] The device was first used in the clinic setting followed by a 2-week at-home period. Outcomes were compared with and without the device both in-clinic and at-home. Use of the device initially decreased performance measures during training in the clinic setting, but these measures did improve after the at-home period. Tables 6 and 7 provide a summary of the characteristics and results of this trial.

Table 6. Summary of Cross-Over Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions (N=29)	
					Active	Comparator
McGibbon et al (2018)[45,]	US, Canada	4	2015-2017	• Ambulatory adults with MS • Able to walk at least 25 m using assisted devices as needed without human assistance	Keeogo exoskeleton	No exoskeleton

m: meters; MS: multiple sclerosis.

Table 7. Summary of Cross-Over Trial Results

Study	6-Minute Walk Test (Mean [SD])[1]	Timed Up-and-Go (Mean [SD])[1]	Timed Stair Test - Up (Mean [SD])[1]	Timed Stair Test - Down (Mean [SD])[1]	Mean Steps per Day (SD)[2]
McGibbon et al (2018)[45,]	N=29	N=29	N=29	N=29	N=29
Exoskeleton	236.8 m (100.6)	20.5 s (7.5)	17.6 s (8.8)	13.1 s (7.0)	4693.5 (2996.0)
No exoskeleton	259.5 m (100.7)	16.2 s (5.8)	12.7 s (5.9)	15.7 s (7.7)	4425.1 (2897.0)
Change (p-value)	-22.7 (.001)	4.3 (<.001)	4.8 (<.001)	2.6 (.002)	268.4 (.046)

[1]In the clinic setting.
[2]In the home setting.
m: meters; s: seconds; SD: standard deviation.

Case Series

Several case series evaluating various powered exoskeletons for ambulation have been conducted primarily in the inpatient setting for spinal cord injury. These case series were included in the systematic review by Tamburella et al (2022) discussed earlier.

One case series has been conducted to assess the use of the powered exoskeleton in the community setting. van Dijsseldonk et al (2020) assessed the use of ReWalk Personal 6.0 exoskeleton in the community setting for up to 3 weeks of use.[46,] Table 8 summarizes the characteristics of this study. Patients used the ReWalk a median of 9 out of 16 days (primarily for exercise) taking a median of 3226 steps. Overall, the exoskeleton was useful for exercise and social interaction but less useful for assistance with activities of daily living. The mean satisfaction score was 3.7 on a scale of 1 to 5 indicating satisfaction with the device.

Table 8. Summary of Key Case Series Characteristics

Study	Country	Participants	Treatment	Follow-Up
van Dijsseldonk et al (2020)[46,]	The Netherlands	Adults at least 6 months post motor-complete SCI between T1 and L1 (N=14)	ReWalk Personal 6.0 for in-home use after 8 weeks of training	2 to 3 weeks of in-home use

L: lumbar; SCI: spinal cord injury; T: thoracic.

Section Summary: Powered Exoskeleton for Ambulation

Several small studies have evaluated the use of powered exoskeletons for ambulation in individuals with spinal cord injury in the institutional setting. These studies were included in a recently published systematic review that summarized the effects of the powered exoskeleton on walking, quality of life, and other secondary health conditions; however, the heterogeneity of outcome measures hindered authors from making general conclusions. One RCT, a randomized cross-over study, and a case series have assessed the use of powered exoskeletons in the home/community setting. Although these studies indicate that powered exoskeletons may be used safely in the outpatient setting, further research is necessary to assess efficacy and safety of the technology. High-quality, comparative studies are needed to determine the benefits of powered exoskeletons for ambulation both in institutional and community settings.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Physical Therapy Association

The American Physical Therapy Association published guidelines in 2020 providing recommendations to guide improvement of locomotor function after brain injury, stroke, or incomplete spinal cord injury in ambulatory patients.[47,] The guidelines recommend against the use of powered exoskeletons for use on a treadmill or elliptical to improve walking speed or distance following acute-onset central nervous system injury in patients more than 6 months post-injury due to minimal benefit and increased costs and time.

A 2022 article by Hohl et al comments on how this guideline recommendation adds uncertainty to the clinical application of powered exoskeletons in rehabilitation.[48,] Several studies referenced in the guideline did not use the Food and Drug Administration (FDA)-approved devices discussed in this review; rather, the guideline focused on treadmill-based robots, specifically the Lokomat®. Therefore, the conclusions should be interpreted with caution, given the substantial differences in functionality and physical demand between the treadmill-based robots and the powered exoskeletons of interest. Taking into consideration the limited guidance on proper use of powered exoskeletons, Hohl et al developed a framework for clinical utilization of powered exoskeletons in rehabilitation settings. The aims of the framework are to: 1) assist practitioners with clinical decision making of when exoskeleton use is clinically indicated, 2) help identify which device is most appropriate based on patient deficits and device characteristics, 3) provide guidance on dosage parameters within a plan of care, and 4) provide guidance for reflection following utilization. The framework focuses specifically on clinical application, not use of powered exoskeletons for personal mobility.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 9.

Table 9. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT05187650	Effectiveness of a Powered Exoskeleton Combined With Functional Electric Stimulation for Patients With Chronic Spinal Cord Injury: a Randomized Controlled Trial	34	Dec 2025 (recruiting)
NCT01701388	Investigational Study of the Ekso Powered Exoskeleton for Ambulation in Individuals With Spinal Cord Injury (or Similar Neurological Weakness)	40	Dec 2023 (active, not recruiting)
NCT04786821	Feasibility Study for a Randomised Control Trial for the Acceptability of Exoskeleton Assisted Walking Compared to Standard Exercise Training for Persons With Mobility Issues Due to Multiple Sclerosis	24	Mar 2024 (recruiting)
Unpublished			
NCT04221373	Exoskeletal-Assisted Walking in SCI Acute Inpatient Rehabilitation	32	Jul 2022 (completed)
NCT03082898	Mobility and Therapeutic Benefits Resulting From Exoskeleton Use in a Clinical Setting (SC140121 Study 1 and 2)	41 (actual enrollment)	Jun 2020 (completed)
NCT02658656	Exoskeleton Assisted-Walking in Persons with SCI (PEPSCI): Impact on Quality of Life	424 (actual enrollment)	Sep 2021 (completed)

NCT: national clinical trial; SCI: spinal cord injury.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	None	
HCPCS	E0739	Rehab system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors ***(Code effective 04/01/2024)***

Type	Code	Description
HCPCS	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

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
06/01/2016	BCBSA Medical Policy Adoption
05/01/2017	Policy revision without position change
05/01/2018	Policy revision without position change
05/01/2019	Policy revision without position change
05/01/2020	Annual review. No change to policy statement. Literature review updated.
05/01/2021	Annual review. No change to policy statement. Policy guidelines and literature review updated. Coding Update.
06/01/2022	Annual review. No change to policy statement. Policy guidelines and literature review updated.
05/01/2023	Annual review. Policy statement and literature review updated.
05/01/2024	Annual review. No change to policy statement. Policy guidelines and literature review updated. Coding Update.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. 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 covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities 1.03.04 **Policy Statement:** I. Use of a powered exoskeleton for ambulation in individuals with lower-limb disabilities is considered **investigational**.	**Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities 1.03.04** **Policy Statement:** I. Use of a powered exoskeleton for ambulation in individuals with lower-limb disabilities is considered **investigational**.