1.03.04	Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities		
Original Policy Date:	June 1, 2016	**Effective Date:**	May 1, 2021
Section:	1.0 Durable Medical Equipment	**Page:**	Page 1 of 11

Policy Statement

Use of a powered exoskeleton for ambulation in patients 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

Effective October 1, 2020, there is a new HCPCS code for this procedure:

- **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

Prior to October 1, 2020, The following unlisted HCPCS code would likely be reported:

- **E1399**: Durable medical equipment, miscellaneous

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 FDA (Class II; FDA product code: PHL). The new classification applies to this device and substantially equivalent devices of this generic type. ReWalk™ 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")
- 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; individuals with spinal cord injuries at levels of C7 to T3.

In 2017, 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 (ASIA 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 stroke patients in rehabilitation settings.

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 (RCTs) 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.

Pre-post study designs (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 patients with lower limb disabilities. The goal of the powered exoskeleton is to enable people 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 question addressed in this evidence review is: Does the use of a powered exoskeleton improve the mobility and net health outcome in patients with lower-limb disabilities?

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

Populations
The relevant population of interest is patients with spinal cord injury. In addition to individuals with spinal cord injury, the powered exoskeleton might be used by those with multiple sclerosis, amyotrophic lateral sclerosis, Guillain-Barré syndrome, and spina bifida.

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

- The Ekso™ GT robotic exoskeleton (now updated to Ekso NR; 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 26 pounds.
- ReWalk (ReWalk Robotics) consists of an onboard computer, sensor array, and the rechargeable batteries that power the exoskeleton, which are contained in a backpack. The complete ReWalk system weighs about 16 kg (35 lb).
- The X1 Mina Exoskeleton is a joint project of NASA Johnson Space Center and the Florida Institute for Human and Machine Cognition. It is being 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 stroke patients 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 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).

Comparator
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

Randomized Crossover Trial
One small (N=29), randomized, open-label, cross-over study evaluated the Keeogo exoskeleton for patients with multiple sclerosis.[4] 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 1 and 2 provide a summary of the characteristics and results of this trial.

Table 1. Summary of Cross-Over Trial Characteristics

Study	Countries	Sites	Dates	Participants	Interventions (N=29)	
					Active	**Comparator**
McGibbon (2018)[4]	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

MS: multiple sclerosis.

Table 2. 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 (2018)[4]	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 (p=.001)	4.3 (p<.001)	4.8 (p<.001)	2.6 (p=.002)	268.4 (p=.046)

[1]In the clinic setting.
[2]In the home setting.
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. Table 3 provides a summary of the characteristics of key case series.

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.[5] 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 1 to 5 scale indicating satisfaction with the device.

Tefertiller et al (2018) evaluated the Indego device in nonambulatory patients.[6] Outcomes improved from midpoint of training to the end of training. Indoor walk speed increased from an average of 0.31 m/s at midpoint to 0.37 m/s at final evaluation. The 6 minute walk test improved from an average of 92 m to 107.5 m at the final evaluation. A total of 66 adverse events were reported with 11 deemed device related. The adverse events were primarily skin irritation, redness, or bruising due to the device. The Indego powered exoskeleton was also evaluated after 5 training sessions (lasting 1.5 hours each for 5 consecutive days) in 16 patients with spinal cord injury between C5 and L1.[7] Testing included the 6 minute walk test and 10 meter walk test. Following training, patients with motor complete tetraplegia (C5-C7 injury level) were able to ambulate on indoor surfaces (hard flooring, carpet, and thresholds), outdoor surfaces (sidewalks), elevators, and ramps, using a walker with assistance from 1 or 2 therapists. In the group of patients with upper paraplegia (T1-T8 injury level), all were able to walk on indoor surfaces, outdoor surfaces, and in elevators; and most were successfully tested on ramps. Among the 8 patients with lower paraplegia (T9-L1 injury level), 6 were able to walk without assistance on indoor surfaces, outdoor surfaces, elevators, ramps, and grass, and 2 required minimal assistance from a therapist.

Bach Baungaard et al (2018) evaluated robotic exoskeletons from Ekso Bionics (Ekso and Ekso GT) at 9 European rehabilitation centers.[8] There were no serious adverse events but 3 patients withdrew due to overuse injuries and 4 patients developed pressure ulcers from the device. Initially 20% of patients who were less than 1 year after injury had gait function without the exoskeleton and this increased to 56% of patients after exoskeleton training (p=0.004). In patients who were more than 1 year post-injury, 41% had gait function without the exoskeleton at baseline and only 1 additional patient (for a total of 44%) gained gait function after training.

Esquenazi et al (2012) published a safety and efficacy trial of the ReWalk in 12 subjects with motor complete thoracic spinal cord injury.[9] All had lower-limb bone and joint integrity, adequate joint range of motion, and a history of standing (either with lower-limb bracing or a standing frame) on a frequent basis. Over 8 weeks, subjects received up to 24 sessions of training lasting 60 to 90 minutes per session that included stepping, sit-to-stand, standing, and stand-to-sit transfers. During this time, unsupervised use of the exoskeleton was not allowed. All 12 participants completed training and were able to independently transfer and walk for at least 50 to 100 meters for a period of at least 5 to 10 minutes. Participants did occasionally lose their balance and either caught themselves with their crutches or were stabilized by the physical therapist. With monitoring of walking, there were no serious adverse events such as falls, bone fractures, or episodes of autonomic dysreflexia. Self-reported health benefits collected at the end of training from 11 subjects included reduced spasticity (n=3) and improved bowel regulation (n=5).

Table 3. Summary of Key Case Series Characteristics

Study	Country	Participants	Treatment	Follow-Up
Esquenazi (2012)[9]	US	Adults at least 6 months post motor-complete SCI between C7-T12 (N=12)	ReWalk	8 weeks of training with follow-up at about 1 year

Study	Country	Participants	Treatment	Follow-Up
Hartigan (2015)[7]	US	Adults with SCI ranging from C5 complete to L1 incomplete (N=16)	Indego	5 training sessions
Bach Baungaard (2018) [8]	Europe	Patients at least 15 years of age and at least 30 days after spinal cord injury (N=52)	Ekso Bionics	8 weeks of training
Tefertiller (2018)[6]	US	Nonambulatory adults with SCI T4 and lower (N=32)	Indego	8 weeks of training
van Dijsseldonk (2020)[5]	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

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

Summary of Evidence

For individuals who have lower-limb disabilities who receive a powered exoskeleton, the evidence includes 1 randomized cross-over study and several case series. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. At the present, evaluation of exoskeletons is limited to small studies primarily performed in institutional settings with patients who have spinal cord injury. These studies have assessed the user's ability to perform, under close supervision, standard tasks such as the Timed Up & Go test, 6-minute walk test, and 10-meter walk test. One randomized, open-label cross-over study and a case series in patients with multiple sclerosis and spinal cord injury, respectively, assessed use of powered exoskeletons in the outpatient setting. Although these small studies indicate powered exoskeletons may be used safely in the outpatient setting, these devices require significant training, and their efficacy has been minimally evaluated. Further evaluation of users' safety with these devices under regular conditions, including the potential to trip and fall should be assessed. Further study is needed to determine the benefits of these devices outside of the institutional setting. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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.[10] 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.

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 trials that might influence this review are listed in Table 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01701388	Investigational Study of the Ekso Powered Exoskeleton for Ambulation in Individuals With Spinal Cord Injury (or Similar Neurological Weakness)	40	Sep 2020 (ongoing)
NCT02658656	Powered Exoskeletons in Persons with SCI (PEPSCI)	160	Sep 2021 (ongoing)
NCT04221373	Exoskeletal-Assisted Walking in SCI Acute Inpatient Rehabilitation	40	Jul 2022 (recruiting)
Unpublished			
NCT03082898	Mobility and Therapeutic Benefits Resulting From Exoskeleton Use in a Clinical Setting (SC140121 Study 1 and 2)	41	Jun 2020 (completed)

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

References

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8. Bach Baunsgaard C, Vig Nissen U, Katrin Brust A, et al. Gait training after spinal cord injury: safety, feasibility and gait function following 8 weeks of training with the exoskeletons from Ekso Bionics. Spinal Cord. Feb 2018; 56(2): 106-116. PMID 29105657
9. Esquenazi A, Talaty M, Packel A, et al. The ReWalk powered exoskeleton to restore ambulatory function to individuals with thoracic-level motor-complete spinal cord injury. Am J Phys Med Rehabil. Nov 2012; 91(11): 911-21. PMID 23085703
10. 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. Jan 2020; 44(1): 49-100. PMID 31834165
11. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 1.03.04 (March 2021).

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	E1399	Durable medical equipment, miscellaneous
	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 ***(Code effective 10/1/2020)***

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.

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 (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.

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:** Use of a powered exoskeleton for ambulation in patients with lower-limb disabilities is considered **investigational**.	**Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities 1.03.04** **Policy Statement:** Use of a powered exoskeleton for ambulation in patients with lower-limb disabilities is considered **investigational**.