



## MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an independent licensee of the Blue Cross and Blue Shield Association

### Medical Policy

## Powered Exoskeleton for Ambulation in Patients with Lower Limb Disabilities

### Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

### Policy Number: 718

BCBSA Reference Number: 1.03.04 (For Plan internal use only)

NCD/LCD: N/A

### Related Policies

- Functional Neuromuscular Electrical Stimulation, #[201](#)
- Microprocessor Controlled Protheses for the Lower Limb, #[133](#)

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

Use of a powered exoskeleton for ambulation in individuals with lower limb disabilities is considered [INVESTIGATIONAL](#).

### Prior Authorization Information

#### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

#### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is <b>not</b> a covered service.
Commercial PPO and Indemnity	This is <b>not</b> a covered service.
Medicare HMO Blue <sup>SM</sup>	This is <b>not</b> a covered service.
Medicare PPO Blue <sup>SM</sup>	This is <b>not</b> a covered service.

### CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

**The following HCPCS codes is considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

### **HCPCS Codes:**

<b>HCPCS codes</b>	<b>Code Description</b>
K1007	Bilateral hip, knee, ankle, foot 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
E0739	Rehab system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors

### **Description**

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 (eg, 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 (eg, 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<sup>1</sup> 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.<sup>2</sup>

### **Summary**

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.

## Summary of Evidence

For individuals who have lower-limb disabilities who receive a powered exoskeleton, the evidence includes 1 systematic review, 1 randomized controlled trial (RCT), 1 randomized cross-over study, and 1 case series describing community use. 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. A recent systematic review included these studies and qualitatively described the effects of powered exoskeletons on walking and on secondary health conditions. However, lack of high-quality studies and heterogeneity of outcome measures precluded the ability to make general conclusions. Evidence on the use of powered exoskeletons in the community or home setting is even more limited. A recent RCT compared quality of life measures in patients with spinal cord injury using in-home powered exoskeleton plus wheelchair versus wheelchair alone, and reported similar results between both groups. In addition, 1 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 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, is necessary. Additional studies, particularly high-quality RCTs, are needed to determine the benefits of these devices both inside and outside of the institutional setting. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## Policy History

Date	Action
5/2024	Annual policy review. References updated. Policy statements unchanged.
4/2024	Clarified coding information.
5/2023	Annual policy review. Minor editorial refinements to policy statements; intent unchanged.
4/2022	Annual policy review. Policy statements unchanged.
4/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
10/2020	Clarified coding information
5/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2017	Annual policy review. New references added.
4/2016	Annual policy review. New references added.
5/2015	New medical policy describing investigational indications. Effective 5/1/2015.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

## References

1. Zeilig G, Weingarden H, Zwecker M, et al. Safety and tolerance of the ReWalk™ exoskeleton suit for ambulation by people with complete spinal cord injury: a pilot study. J Spinal Cord Med. Mar 2012; 35(2): 96-101. PMID 22333043

2. Asselin P, Knezevic S, Kornfeld S, et al. Heart rate and oxygen demand of powered exoskeleton-assisted walking in persons with paraplegia. *J Rehabil Res Dev.* 2015; 52(2): 147-58. PMID 26230182
3. Lajeunesse V, Vincent C, Routhier F, et al. Exoskeletons' design and usefulness evidence according to a systematic review of lower limb exoskeletons used for functional mobility by people with spinal cord injury. *Disabil Rehabil Assist Technol.* Oct 2016; 11(7): 535-47. PMID 26340538
4. Tamburella F, Lorusso M, Tramontano M, et al. Overground robotic training effects on walking and secondary health conditions in individuals with spinal cord injury: systematic review. *J Neuroeng Rehabil.* Mar 15 2022; 19(1): 27. PMID 35292044
5. Chun A, Asselin PK, Knezevic S, et al. Changes in bowel function following exoskeletal-assisted walking in persons with spinal cord injury: an observational pilot study. *Spinal Cord.* Apr 2020; 58(4): 459-466. PMID 31822808
6. McIntosh K, Charbonneau R, Bensaada Y, et al. The Safety and Feasibility of Exoskeletal-Assisted Walking in Acute Rehabilitation After Spinal Cord Injury. *Arch Phys Med Rehabil.* Jan 2020; 101(1): 113-120. PMID 31568761
7. Tsai CY, Delgado AD, Weinrauch WJ, et al. Exoskeletal-Assisted Walking During Acute Inpatient Rehabilitation Leads to Motor and Functional Improvement in Persons With Spinal Cord Injury: A Pilot Study. *Arch Phys Med Rehabil.* Apr 2020; 101(4): 607-612. PMID 31891715
8. Gagnon DH, Vermette M, Duclos C, et al. Satisfaction and perceptions of long-term manual wheelchair users with a spinal cord injury upon completion of a locomotor training program with an overground robotic exoskeleton. *Disabil Rehabil Assist Technol.* Feb 2019; 14(2): 138-145. PMID 29256640
9. Guanziroli E, Cazzaniga M, Colombo L, et al. Assistive powered exoskeleton for complete spinal cord injury: correlations between walking ability and exoskeleton control. *Eur J Phys Rehabil Med.* Apr 2019; 55(2): 209-216. PMID 30156088
10. Khan AS, Livingstone DC, Hurd CL, et al. Retraining walking over ground in a powered exoskeleton after spinal cord injury: a prospective cohort study to examine functional gains and neuroplasticity. *J Neuroeng Rehabil.* Nov 21 2019; 16(1): 145. PMID 31752911
11. Kressler J, Domingo A. Cardiometabolic Challenges Provided by Variable Assisted Exoskeletal Versus Overground Walking in Chronic Motor-incomplete Paraplegia: A Case Series. *J Neurol Phys Ther.* Apr 2019; 43(2): 128-135. PMID 30883500
12. Kubota S, Abe T, Kadone H, et al. Hybrid assistive limb (HAL) treatment for patients with severe thoracic myelopathy due to ossification of the posterior longitudinal ligament (OPLL) in the postoperative acute/subacute phase: A clinical trial. *J Spinal Cord Med.* Jul 2019; 42(4): 517-525. PMID 30335588
13. Manns PJ, Hurd C, Yang JF. Perspectives of people with spinal cord injury learning to walk using a powered exoskeleton. *J Neuroeng Rehabil.* Jul 19 2019; 16(1): 94. PMID 31324256
14. van Dijsseldonk RB, Rijken H, van Nes IJW, et al. Predictors of exoskeleton motor learning in spinal cord injured patients. *Disabil Rehabil.* Jul 2021; 43(14): 1982-1988. PMID 31724882
15. Alamro RA, Chisholm AE, Williams AMM, et al. Overground walking with a robotic exoskeleton elicits trunk muscle activity in people with high-thoracic motor-complete spinal cord injury. *J Neuroeng Rehabil.* Nov 20 2018; 15(1): 109. PMID 30458839
16. 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
17. Baunsgaard CB, Nissen UV, Brust AK, et al. Exoskeleton gait training after spinal cord injury: An exploratory study on secondary health conditions. *J Rehabil Med.* Sep 28 2018; 50(9): 806-813. PMID 30183055
18. Cahill A, Ginley OM, Bertrand C, et al. Gym-based exoskeleton walking: A preliminary exploration of non-ambulatory end-user perspectives. *Disabil Health J.* Jul 2018; 11(3): 478-485. PMID 29500092
19. Chang SH, Afzal T, Berliner J, et al. Exoskeleton-assisted gait training to improve gait in individuals with spinal cord injury: a pilot randomized study. *Pilot Feasibility Stud.* 2018; 4: 62. PMID 29556414
20. Escalona MJ, Brosseau R, Vermette M, et al. Cardiorespiratory demand and rate of perceived exertion during overground walking with a robotic exoskeleton in long-term manual wheelchair users with chronic spinal cord injury: A cross-sectional study. *Ann Phys Rehabil Med.* Jul 2018; 61(4): 215-223. PMID 29371106

21. Gagnon DH, Escalona MJ, Vermette M, et al. Locomotor training using an overground robotic exoskeleton in long-term manual wheelchair users with a chronic spinal cord injury living in the community: Lessons learned from a feasibility study in terms of recruitment, attendance, learnability, performance and safety. *J Neuroeng Rehabil.* Mar 01 2018; 15(1): 12. PMID 29490678
22. Juszczyk M, Gallo E, Bushnik T. Examining the Effects of a Powered Exoskeleton on Quality of Life and Secondary Impairments in People Living With Spinal Cord Injury. *Top Spinal Cord Inj Rehabil.* 2018; 24(4): 336-342. PMID 30459496
23. Ramanujam A, Ciriogliaro CM, Garbarini E, et al. Neuromechanical adaptations during a robotic powered exoskeleton assisted walking session. *J Spinal Cord Med.* Sep 2018; 41(5): 518-528. PMID 28427305
24. Ramanujam A, Momeni K, Husain SR, et al. Mechanisms for improving walking speed after longitudinal powered robotic exoskeleton training for individuals with spinal cord injury. *Annu Int Conf IEEE Eng Med Biol Soc.* Jul 2018; 2018: 2805-2808. PMID 30440984
25. Sale P, Russo EF, Scarton A, et al. Training for mobility with exoskeleton robot in spinal cord injury patients: a pilot study. *Eur J Phys Rehabil Med.* Oct 2018; 54(5): 745-751. PMID 29517187
26. Tefertiller C, Hays K, Jones J, et al. Initial Outcomes from a Multicenter Study Utilizing the Indego Powered Exoskeleton in Spinal Cord Injury. *Top Spinal Cord Inj Rehabil.* 2018; 24(1): 78-85. PMID 29434463
27. Yatsugi A, Morishita T, Fukuda H, et al. Feasibility of Neurorehabilitation Using a Hybrid Assistive Limb for Patients Who Underwent Spine Surgery. *Appl Bionics Biomech.* 2018; 2018: 7435746. PMID 30116296
28. Birch N, Graham J, Priestley T, et al. Results of the first interim analysis of the RAPPER II trial in patients with spinal cord injury: ambulation and functional exercise programs in the REX powered walking aid. *J Neuroeng Rehabil.* Jun 19 2017; 14(1): 60. PMID 28629390
29. Karelis AD, Carvalho LP, Castillo MJ, et al. Effect on body composition and bone mineral density of walking with a robotic exoskeleton in adults with chronic spinal cord injury. *J Rehabil Med.* Jan 19 2017; 49(1): 84-87. PMID 27973679
30. Benson I, Hart K, Tussler D, et al. Lower-limb exoskeletons for individuals with chronic spinal cord injury: findings from a feasibility study. *Clin Rehabil.* Jan 2016; 30(1): 73-84. PMID 25761635
31. Lonini L, Shawen N, Scanlan K, et al. Accelerometry-enabled measurement of walking performance with a robotic exoskeleton: a pilot study. *J Neuroeng Rehabil.* Mar 31 2016; 13: 35. PMID 27037035
32. Platz T, Gillner A, Borgwaldt N, et al. Device-Training for Individuals with Thoracic and Lumbar Spinal Cord Injury Using a Powered Exoskeleton for Technically Assisted Mobility: Achievements and User Satisfaction. *Biomed Res Int.* 2016; 2016: 8459018. PMID 27610382
33. Sale P, Russo EF, Russo M, et al. Effects on mobility training and de-adaptations in subjects with Spinal Cord Injury due to a Wearable Robot: a preliminary report. *BMC Neurol.* Jan 28 2016; 16: 12. PMID 26818847
34. Stampacchia G, Rustici A, Bigazzi S, et al. Walking with a powered robotic exoskeleton: Subjective experience, spasticity and pain in spinal cord injured persons. *NeuroRehabilitation.* Jun 27 2016; 39(2): 277-83. PMID 27372363
35. Kozlowski AJ, Bryce TN, Dijkers MP. Time and Effort Required by Persons with Spinal Cord Injury to Learn to Use a Powered Exoskeleton for Assisted Walking. *Top Spinal Cord Inj Rehabil.* 2015; 21(2): 110-21. PMID 26364280
36. Evans N, Hartigan C, Kandilakis C, et al. Acute Cardiorespiratory and Metabolic Responses During Exoskeleton-Assisted Walking Overground Among Persons with Chronic Spinal Cord Injury. *Top Spinal Cord Inj Rehabil.* 2015; 21(2): 122-32. PMID 26364281
37. Hartigan C, Kandilakis C, Dalley S, et al. Mobility Outcomes Following Five Training Sessions with a Powered Exoskeleton. *Top Spinal Cord Inj Rehabil.* 2015; 21(2): 93-9. PMID 26364278
38. Yang A, Asselin P, Knezevic S, et al. Assessment of In-Hospital Walking Velocity and Level of Assistance in a Powered Exoskeleton in Persons with Spinal Cord Injury. *Top Spinal Cord Inj Rehabil.* 2015; 21(2): 100-9. PMID 26364279
39. Kressler J, Thomas CK, Field-Fote EC, et al. Understanding therapeutic benefits of overground bionic ambulation: exploratory case series in persons with chronic, complete spinal cord injury. *Arch Phys Med Rehabil.* Oct 2014; 95(10): 1878-1887.e4. PMID 24845221

40. Fineberg DB, Asselin P, Harel NY, et al. Vertical ground reaction force-based analysis of powered exoskeleton-assisted walking in persons with motor-complete paraplegia. *J Spinal Cord Med.* Jul 2013; 36(4): 313-21. PMID 23820147
41. KolakowskyHayner SCJ. A. Safety and Feasibility of using the Ekso™ Bionic Exoskeleton to Aid Ambulation after Spinal Cord Injury. *J Spine.* 2013; 4:456.
42. Talaty M, Esquenazi A, Briceno JE. Differentiating ability in users of the ReWalk(TM) powered exoskeleton: an analysis of walking kinematics. *IEEE Int Conf Rehabil Robot.* Jun 2013; 2013: 6650469. PMID 24187286
43. 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
44. Spungen AM, Bauman WA, Biswas K, et al. The design of a randomized control trial of exoskeletal-assisted walking in the home and community on quality of life in persons with chronic spinal cord injury. *Contemp Clin Trials.* Sep 2020; 96: 106102. PMID 32800962
45. McGibbon CA, Sexton A, Jayaraman A, et al. Evaluation of the Keeogo exoskeleton for assisting ambulatory activities in people with multiple sclerosis: an open-label, randomized, cross-over trial. *J Neuroeng Rehabil.* Dec 12 2018; 15(1): 117. PMID 30541585
46. van Dijsseldonk RB, van Nes IJW, Geurts ACH, et al. Exoskeleton home and community use in people with complete spinal cord injury. *Sci Rep.* Sep 24 2020; 10(1): 15600. PMID 32973244
47. 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
48. Hohl K, Giffhorn M., Jackson S, et al. A framework for clinical utilization of robotic exoskeletons in rehabilitation. *J NeuroEngineering Rehabil.* 2022;19(1). Article number 115.