BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 1.03.04 Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities

Annual Effective Policy Date: July 1, 2024

Original Policy Date: June 2015

Related Policies:

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

Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities

Description

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-Barr syndrome, and spina bifida.

OBJECTIVE

The objective of this evidence review is to determine whether use of a powered exoskeleton improves mobility and net health outcomes for individuals with lower-limb disabilities.

POLICY STATEMENT

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

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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)

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

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

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.

SUPPLEMENTAL INFORMATION

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.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

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.

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

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

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. Juszczak 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, Cirnigliaro 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 EksoTM 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

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

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.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2015	New policy	Policy created with literature review; considered not medically necessary.
March 2017	Replace policy	Policy updated with literature review; references 2, 3, 6, and 7 added. Policy statement unchanged.
June 2018	Replace policy	Policy updated with literature review through January 8, 2018; no references added. Policy statement unchanged except "not medically necessary€š corrected to "investigational€š due to FDA 510k status.
June 2019	Replace policy	Policy updated with literature review through January 6, 2019; no references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through January 30, 2020; no references added. Policy statement unchanged.
June 2021	Replace policy	Policy updated with literature review through January 25, 2021; references added. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through January 11, 2022; no references added. Policy statement unchanged.
June 2023	Replace policy	Policy updated with literature review through January 23, 2023; references added. Minor editorial refinements to policy statements; intent unchanged.
June 2024	Replace policy	Policy updated with literature review through January 18, 2024; no references added. Policy statement unchanged.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.