



# Medical Policy

## Powered Robotic Lower Body Exoskeleton Devices

Policy Number: PG0425

Last Review: 12/01/2023

### GUIDELINES

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

### SCOPE

☒ Professional☒ Facility

### DESCRIPTION

Robotic lower body exoskeleton devices are intended to allow individuals with loss of lower limb function to ambulate on their own. When used, the device is worn outside clothing and consists of an upper-body harness, lower-limb braces, motorized joints, ground-force sensors, a tilt sensor, a locomotion-mode selector, and a backpack carrying a computerized controller and rechargeable battery. Using a wireless remote control worn on the wrist, the user commands the device to stand up, sit down, or walk. The device is strapped to the user at the waist, alongside each lower limb, and at the feet. Ordinary crutches are also utilized to help maintain stability.

Use of lower limb electromechanical exoskeleton devices have been proposed to assist in ambulation and rehabilitation for a variety of conditions, including spinal cord injury (SCI), traumatic brain injury (TBI), stroke, multiple sclerosis (MS), and others. Generally, the use of these devices requires that individuals can stand using an assistive device (e.g., standing frame) and their hands and shoulders are able to support crutches or a walker. None of these types of devices are intended for sports or climbing stairs.

Examples of these types of devices include, but may not be limited to, the following:

- ReWalk™ (ReWalk Robotics, Marlborough, MA) consists of an onboard computer, sensor array, and the rechargeable batteries that power the exoskeleton which are contained in a backpack. The complete system weighs about 35 pounds.
- Indego® powered exoskeleton (also known as the Vanderbilt exoskeleton; Parker Hannifin, Macedonia, OH) is used for gait training and is now available for home use. It includes functional electrical stimulation and weighs 26 pounds.
- Ekso™ GT robotic exoskeleton (Ekso Bionics, Richmond, CA) is available for institutional use for rehabilitation. It is undergoing testing for personal use for ambulation in several registered trials.
- 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 57 pounds.

To date, evaluation of the powered exoskeleton available studies has been limited to the research setting. Further

study is needed to determine whether these devices can be successfully used outside of the investigational (laboratory) setting. Long-term outcomes, including quality of life and clinical improvement overall, have not been reported in the medical literature. Currently, evidence in the peer reviewed published scientific literature remains insufficient to firmly establish clinical utility and improved long-term health benefits.

## POLICY

### **Paramount Commercial Insurance Plans and Medicare Advantage Plans**

- **Powered, robotic lower body exoskeleton devices (K1007) are non-covered.**

## COVERAGE CRITERIA

### **Paramount Commercial Insurance Plans and Medicare Advantage Plans**

The use of the robotic lower body exoskeleton device is unproven and therefore non-covered in all settings/levels of care in patients with conditions which impair the ability to ambulate (e.g., spinal cord injury, stroke, Parkinson's disease, etc.) due to insufficient clinical evidence of safety and/or efficacy in published peer-reviewed medical literature.

Paramount does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and their patient. Paramount administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another and is not intended to represent a complete listing of all products available.

## CODING/BILLING INFORMATION

The inclusion or exclusion of a code in this section does not necessarily indicate coverage. Codes referenced in this clinical policy are for informational purposes only.

Codes that are covered may have selection criteria that must be met.

Payment for supplies may be included in payment for other services rendered.

HCPCS CODE	
<b>K1007</b>	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
<b>L2999</b>	Lower extremity orthoses, not otherwise specified

## REVISION HISTORY EXPLANATION

### **ORIGINAL EFFECTIVE DATE: 02/22/2018**

Date	Explanation & Changes
<b>02/22/2018</b>	<ul style="list-style-type: none"><li>• Powered, robotic lower body exoskeleton devices are non-covered</li><li>• Policy created to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG)</li></ul>
<b>12/28/2020</b>	<ul style="list-style-type: none"><li>• Medical policy placed on the new Paramount Medical policy format</li></ul>
<b>03/03/2023</b>	<ul style="list-style-type: none"><li>• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023</li></ul>
<b>12/01/2023</b>	<ul style="list-style-type: none"><li>• Medical Policy reviewed and updated to reflect the most current clinical evidence</li><li>• Added non-covered HCPCS code K1007</li></ul>

**Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to.**

<https://www.paramounthealthcare.com/providers/medical-policies/policy-library>

## REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals> <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs>

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services <https://www.ama-assn.org/amaone/cpt-current-procedural-terminology>

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

Hayes, Inc., <https://www.hayesinc.com/>

Industry Standard Review

## POLICY

### **Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid**

**Powered, robotic lower body exoskeleton devices are non-covered.**

## COVERAGE CRITERIA

### **Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid**

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CPT CODE	
L2999	Lower extremity orthoses, not otherwise specified