

# Regence

## Powered Exoskeleton for Ambulation and Rehabilitation

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### IMPORTANT REMINDER

*The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.*

*The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.*

*Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.*

## DESCRIPTION

A powered exoskeleton for ambulation 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. It consists of an exoskeleton-like framework worn by a person that includes a power source supplying energy for limb movement. They are designed 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. Powered exoskeletons for rehabilitation are designed to provide therapist-assisted and remote robot-assisted repetitive task physical therapy. The devices have the potential to restore mobility and, thus, might improve functional status, quality of life, and health status for such patients.

## MEDICARE ADVANTAGE POLICY CRITERIA

<b>CMS Coverage Manuals*</b>	None
<b>National Coverage Determinations (NCDs)*</b>	None While there is no specific Medicare guidance for exoskeleton devices, Medicare does provide general coverage requirements for mobility assistive equipment (MAE) and durable medical equipment (DME). <sup>[1,2]</sup>
<b>Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*</b>	None
<b>Medical Policy Manual</b>	<i>Medicare coverage guidance is not available for powered exoskeleton devices used for ambulation. Therefore, the health plan's medical policy is applicable.</i>  Powered Exoskeleton for Ambulation and Rehabilitation, Durable Medical Equipment, <a href="#">Policy No. 89</a> (see "NOTE" below)

**NOTE:** If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. ([Medicare IOM Pub. No. 100-04, Ch. 23, §30 A](#)). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an **objective, evidence-based process, based on authoritative evidence**. ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

## POLICY GUIDELINES

### REGULATORY STATUS

The following are devices Commercially available:

DEVICE	MANUFACTURER
Rewalk™	ReWalk Robotics, previously Argo Medical Technologies
Indego®	Parker Hannifin Corp.
Ekso™	Ekso Bionics® Inc.
Ekso GT™	Ekso Bionics® Inc.
EksoNR™	Ekso Bionics® Inc.

HAL for Medical Use (Lower Limb Type)	CYBERDYNE Inc.
Keeogo™	B-Temia
PhoeniX™	DBA SuitX
ExoAtlet-II®	ExoAtlet Asia Co. Ltd.
Atalante®	Wandercraft SAS
GEMS-H®	Samsung Electronics Co. Ltd.
Motus Hand and Motus Foot	Motus Nova

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

## CROSS REFERENCES

[Definitive Lower Limb Prostheses](#), DME, Policy No. M-18

[Upper Extremity Rehabilitation System with Brain-Computer Interface](#), DME, Policy No. M-94

[Investigational \(Experimental\) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services](#), Medicine, Policy No. M-149

## REFERENCES

1. NCD for *Mobility Assistive Equipment* (MAE) ([280.3](#)) [Last Cited 09/20/2024]
2. NCD for *Durable Medical Equipment Reference List* ([280.1](#)) [Last Cited 09/20/2024]
3. Palmetto GBA Pricing, Data and Coding (PDAC) web page for *Retired - Correct Coding - Powered Exoskeleton Products*; Available at: <https://www.dmepdac.com/palmetto/PDACv2.nsf/DIDC/X0YEA9TWDB~Articles%20and%20Publications~Advisory%20Articles%20-%20Retired> [Last Cited 09/20/2024]
4. Noridian web page for *RETIRED - Correct Coding - Powered Exoskeleton Products*; Available at: <https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/powered-exoskeleton-products> [Last Cited 09/20/2024]

## CODING

**NOTE:** Powered exoskeletons such as the Rewalk™ (Argo Technologies) and Indego® (Parker Hannifin Corp.) devices, were previously instructed to be reported with A9270 (*Non-covered item or service*) by Medicare PDAC contractors.<sup>[3,4]</sup> HCPCS code E1399 was not appropriate for use for Medicare.

Codes	Number	Description
CPT	None	

<b>HCPCS</b>	A9270	Non-covered item or service
	E0739	Rehabilitation system with interactive interface providing active assistance in rehabilitation therapy, includes all components and accessories, motors, microprocessors, sensors
	E1399	Durable medical equipment, miscellaneous
	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

**\*IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.