Medical Policy

Northwood

Powered Exoskeleton Orthosis

Description

A powered exoskeleton orthosis is a wearable, robotic exoskeleton device that provides powered hip and knee motion to enable individuals with a spinal cord injury (SCI) to stand upright, walk, turn, and climb and descend stairs. The system allows independent, controlled walking while mimicking the natural gait pattern of the legs.

This orthotic device (e.g., trunk-hip-knee-ankle-foot device) was designed with the intent of assisting individuals with spinal cord injuries and other lower-limb impairments to ambulate. These devices employ the use of computer-controlled, motorized leg-braces that assist with restoring ambulation. Individual patient selection criteria are very specific, and use of the device requires coordinated and structured rehabilitation prior to and during home use.

The FDA describes/categorizes a powered exoskeleton as a prescription device composed of an external, powered, motorized orthosis used for medical purposes that is placed over a person's paralyzed or weakened limbs for the purpose of providing ambulation. With a wrist-pad controller the user can activate the robotics system to stand, sit, or start walking, and with a torso tilt sensor, the user can trigger step to step transition during walking. Several robotic lower body exoskeleton devices have been approved by the FDA, including the ReWalk exoskeleton, Ekso, Ekso GT, and the Indego.

In theory, the devices restore mobility, increase function, and improve health status and quality of life. In addition to medical necessity criteria established by the manufacturer and FDA approval trials, use of the device requires a lengthy training period with a skilled physical therapist licensed for training with the device, a dedicated caregiver to assist with the device, access to a facility that offers a rehabilitation program for the device, and complex rehabilitation provided over several weeks to months.

Policy

A powered exoskeleton device is considered experimental, investigational or unproven (e.g., ReWalk Personal System).

HCPCS Level II Codes and Description

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 (Code effective 10/1/20).

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General Indications and Limitations of Coverage and/or Medical Necessity

For a DMEPOS item to be covered, it must 1) be eligible for a defined benefit category and 2) be reasonable and necessary for the treatment of illness or injury or improve the functioning of a malformed body member or used to replace all or part of a body part or all or part of the functions of a permanently disabled or poorly functioning body organ. For the items addressed in medical policy, the criteria for "reasonable and necessary" are defined by the carrier or plan sponsor's indications and limitations of coverage and/or medical necessity.

Certain statutory and/or regulatory requirements may be applicable to the carrier or plan sponsor which may affect coverage or benefits (e.g., certain states mandate coverage of, or waiver of co-payments for, diabetic/glucose monitoring supplies, prosthetic wigs, etc.).

References

1. Cigna: Orthotic Devices and Shoes https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0543_coveragepositioncriteria_orthotic_devices_shoes.pdf Accessed and reviewed December 5, 2024.

2. Esquenazi A, Talaty M, Packel A, Saulino M. The ReWalk powered exoskeleton to restore ambulatory function to individuals with thoracic-level motor-complete spinal cord injury. Am J Phys Med Rehabil. 2012 Nov;91(11):911-21.

Important Note

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

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The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Northwood follows all CMS National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), as applicable.

Change/Authorization History

Revision Number	Effective Date	Date	Description of Change	Prepared / Reviewed by	Approved by	Review Date:
A	10-1-20	9-30-20	Initial Release	Carol Dimech	Dr. C. Lerchin	N/A
1	12-14-21	12-14-21	Annual review. Added NCD/LCD verbiage to Important Note.	Carol Dimech	Dr. C. Lerchin	December 2021
2	12-1-22	12-1-22	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	12-1-22
3	12-7-23	12-7-23	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	12-7-23
4	12-5-24	12-5-24	Annual review. No changes.	Carol Dimech	Dr. C. Lerchin	12-5-24