Clinical Review Criteria
Exoskeleton

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Criteria
For Medicare Members

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<th>Source</th>
<th>Policy</th>
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<tr>
<td>CMS Coverage Manuals</td>
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<td>National Coverage Determinations (NCD)</td>
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<td>Local Coverage Article</td>
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For Non-Medicare Members
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting this service, please send the following documentation to support medical necessity:
- Last 3 months of clinical notes from requesting provider &/or consulting specialist.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
The CDC estimates that there are about 200,000 people in the United States (US) living with a spinal cord injury (SCI) (CDC 2014). Depending on the vertebral level and the degree of completeness, SCI can result in a variety of degrees of neurological deficit. Individuals with traumatic, motor-complete SCI abruptly lose the ability to stand and walk, relying on wheelchairs as a means of locomotion. Eventually, extreme inactivity causes rapid and marked alteration in body composition and can lead to additional complications such as ulcers, weakened bones, digestive disorders, and urinary tract infections (UTI). To add to this, the loss of mobility can negatively impact a patient’s quality of life (QoL) and places SCI patients at higher risk for secondary medical conditions such as, diabetes and cardiovascular disease, to name a few (Spungen, Asselin et al. 2013).

A variety of techniques have been attempted to restore walking abilities with limited success. The concept of exoskeletons was first introduced in Russia in 1890, however, the first true exoskeleton was developed in the US, for military use, and consisted of an outer framework for the lower extremities powered by motors and hydraulics to deliver at least part of the energy for movement. When applied, the device was intended to enable soldiers to carry heavy objects while running or climbing stairs. Several different prototypes have been developed for the military, however, none have been able to overcome a variety of technological limitations such as power source and joint flexibility. In more recent years, the concept of an exoskeleton has been applied in the medical field to aid in the rehabilitation of patients with loss of motor function due to stroke or SCI (Talaty, Esquenazi et al. 2013). Currently, several devices have been developed for this indication, however, only one company, Argo Medical Technologies, Inc. (Marlborough, MA), has received clearance for marketing in the United States (US).

The ReWalk™ was designed to allow patients with paraplegia, due to SCI, to fully weight bear while standing and to ambulate over ground. In its entirety, the system includes two leg braces with motorized joints and motion
sensors, a harness, and a backpack for holding the computer that controls the device as well as a battery that is estimated to last for three to four hours. The device can facilitate standing, walking, and sitting modes and operates by powering hip and knee motion allowing patients functional and independent walking with the use of lofstrand forearm crutches to maintain balance. Use of the ReWalk™ requires training in a rehabilitation setting (Zeilig, Weingarden et al. 2012).

Medical Technology Assessment Committee (MTAC)
02/09/2015: MTAC REVIEW

Exoskeleton

Evidence Conclusion: The literature search revealed only a small number of publications relating to the exoskeleton. No randomized controlled trials (RCT) comparing exoskeletons to wheelchairs were revealed. The FDA’s approval relied on three observational studies that assessed the safety and tolerance of the ReWalk. In each of the studies, patients were trained to use the device in a clinical setting under the guidance of a physical therapist. Upon training completion (approximately 8 weeks), subjects underwent performance evaluations. None of the studies were carried out in a home-setting or assessed long-term performance. No studies were selected for critical appraisal due to methodological limitations such as study design and small sample size. An extensive list of ongoing studies relating to exoskeletons was revealed after searching in the National Institute of Health’s clinical trials database. Conclusions: There is insufficient evidence to support the effectiveness of exoskeleton suits for ambulation compared to wheelchairs. There is insufficient evidence to support the safety of exoskeleton suits for ambulation compared to wheelchairs.

Articles: The literature search revealed only a small number of publications relating to the exoskeleton. No randomized controlled trials (RCT) comparing exoskeletons to wheelchairs were revealed. The FDA’s approval relied on three observational studies that assessed the safety and tolerance of the ReWalk. In each of the studies, patients were trained to use the device in a clinical setting under the guidance of a physical therapist. Upon training completion (approximately 8 weeks), subjects underwent performance evaluations. None of the studies were carried out in a home-setting or assessed long-term performance. No studies were selected for critical appraisal due to methodological limitations such as study design and small sample size. An extensive list of ongoing studies relating to exoskeletons was revealed after searching in the National Institute of Health’s clinical trials database.

The use of Exoskeleton does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

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MPC Medical Policy Committee

Revision History

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Codes

No codes provided