FEP Medical Policy Manual

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

Effective Policy Date: July 1, 2020
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

The ReWalk and Indego are powered exoskeletons that provide user-initiated mobility. 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-Barré syndrome, and spina bifida.

OBJECTIVE

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

POLICY STATEMENT

Use of a powered exoskeleton for ambulation in patients with lower-limb disabilities is considered investigative.
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™ 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"-6'2")
- Weight does not exceed 100 kg (220 lb).

The FDA is requiring ReWalk’s manufacturer to complete a postmarket clinical study (PS14001) that will consist of a registry to collect data on adverse events related to the use of the ReWalk™ device and prospectively and systematically assess the adequacy of its training program.

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; individuals with spinal cord injuries at levels of C7 to T3.

In 2017, 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 (ASIA C, ASIA D) and T11 to L5 (ASIA A with Zones of Partial Preservation, ASIA B)

FDA product code: PHL.

RATIONALE

Summary of Evidence

For individuals who have lower-limb disabilities who receive a powered exoskeleton, the evidence includes case series. Relevant outcomes are functional outcomes, quality of life, and treatment-related morbidity. At the present, evaluation of exoskeletons is limited to small studies 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 2016 report from the Veterans Administration has suggested that over 60 training sessions may be needed to achieve proficiency with both indoor and outdoor mobility, including door/threshold navigation, stopping, turning, and reaching. There are concerns about users’ safety with these devices under regular conditions, including the potential to trip and fall. Further study is needed to determine whether these devices can be successfully used outside of the institutional setting. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

No guidelines or statements were identified.

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


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

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>June 2015</td>
<td>New policy</td>
<td>Policy created with literature review; considered not medically necessary.</td>
</tr>
<tr>
<td>March 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references 2, 3, 6, and 7 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>June 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 8, 2018; no references added. Policy statement unchanged except &quot;not medically necessary&quot; corrected to &quot;investigational&quot; due to FDA 510k status.</td>
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<tr>
<td>June 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 6, 2019; no references added. Policy statement unchanged.</td>
</tr>
<tr>
<td>June 2020</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 30, 2020; no references added. Policy statement unchanged.</td>
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