Introduction

The word exoskeleton means a skeleton that’s outside of the body. In healthcare, an exoskeleton is a robotic system that a person wears. It’s a frame that a person wears on the lower part of the body, and it has joints that are intended to mimic how the body works when walking. Exoskeletons have a power supply that moves the limbs. For people who don’t have the ability to control their legs, the goal of an exoskeleton is to help them stand, walk, and use stairs. There are a few small studies that have been published about exoskeletons. These studies looked at only a small number of people with spinal cord injuries who used these devices within an institution, like a hospital. There are concerns about how safe they are when used outside of a hospital or similar setting. These concerns include the possibility of tripping and falling. More studies are needed to find out if exoskeletons are safe. For these reasons, exoskeletons are considered unproven (investigational).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Policy Coverage Criteria

Device | Investigational
---|---
**Powered exoskeleton** | Use of a powered exoskeleton for ambulation in patients with lower-limb disabilities is considered investigational. This includes but is not limited to the following:
- The ReWalk system
- Ekso™
- Indego®
- All others

Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
</tr>
<tr>
<td>K1007</td>
<td>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 (New code effective 10/1/20)</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

N/A

Evidence Review
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. These 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.

Background

An exoskeleton 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. A powered exoskeleton, as described in this evidence review, consists of an exoskeleton-like framework worn by a person that includes a power source supplying energy for limb movement.

One type of powered lower-limb exoskeleton (eg, ReWalk, Indego) provides user-initiated mobility based on postural information. Standing, walking, sitting, and stair up/down modes are determined by a mode selector on a wristband. ReWalk includes an array of sensors and proprietary algorithms that analyze body movements (eg, tilt of the torso) and manipulate the motorized leg braces. The tilt sensor is used to signal the on-board computer when to take the next step. Patients using the powered exoskeleton must be able to use their hands and shoulders with forearm crutches or a walker to maintain balance. Instructions for ambulating with ReWalk\(^1\) are to place the crutches ahead of the body, and then bend the elbows slightly, shifting weight toward the front leg, leaning toward the front leg side. The rear leg will lift slightly off of the ground and then begin to move forward. Using the crutches to straighten up will enable the rear leg to continue moving forward. The process is repeated with the other leg.

To move from a seated to standing position or vice versa, the desired movement is selected by the mode selector on the wrist. There is a 5-second delay to allow the individual to shift weight (forward for sit-to-stand and slightly backward for stand-to-sit) and to place their crutches in the correct position. If the user is not in an appropriate position, a safety mechanism will be triggered. Walking can only be enabled while standing, and the weight shift must be sufficient to move the tilt sensor and offload the back leg to allow it to swing forward. Continuous ambulation is accomplished by uninterrupted shifting onto the contralateral leg. The device can be switched to standing either via the mode selector or by not shifting weight laterally for two seconds, which triggers the safety mechanism to stop walking. Some patients have become proficient with ReWalk by the third week of training.\(^2\)
Summary of Evidence

For individuals who have lower-limb disabilities who receive a powered exoskeleton, the evidence includes case series. The relevant outcomes are functional outcomes, quality of life, and treatment-related mobility. 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 and 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.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT01701388</td>
<td>Investigational Study of the Ekso Powered Exoskeleton for Ambulation in Individuals With Spinal Cord Injury (or Similar Neurological Weakness)</td>
<td>40</td>
<td>Sep 2020</td>
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<tr>
<td>NCT03082898</td>
<td>Mobility and Therapeutic Benefits Resulting From Exoskeleton Use in a Clinical Setting (SC140121 Study 1)</td>
<td>24</td>
<td>Dec 2020</td>
</tr>
<tr>
<td>NCT02658656</td>
<td>Exoskeleton Assisted-Walking in Persons With SCI: Impact on Quality of Life</td>
<td>160</td>
<td>Sep 2021</td>
</tr>
<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02202538*</td>
<td>Indego® Exoskeleton; Assessing Mobility for Persons With Spinal Cord Injury (SCI).</td>
<td>45</td>
<td>Oct 2015 (completed)</td>
</tr>
</tbody>
</table>
Medicare National Coverage

There is no national coverage determination.

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; 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-risk 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 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 of 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.

References


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/01/17</td>
<td>New policy approved September 12, 2017, effective January 5, 2018. Add to Durable Medical Equipment section, Orthotic Devices subsection. This service is considered investigational.</td>
</tr>
<tr>
<td>05/01/18</td>
<td>Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018; no references added. Policy statement unchanged.</td>
</tr>
<tr>
<td>10/01/20</td>
<td>Coding update. Added HCPCS code K1007.</td>
</tr>
</tbody>
</table>

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2020 Premera All Rights Reserved.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4735, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartment@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at:
https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
Office for Civil Rights Complaint Portal, available at:

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.
Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):
لا يوجد هذا الإشعار في اللغة العربية.

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本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或接收的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話及 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):

Français (French):

Kreyòl Ayisyen (Creole):
Avi sila a gen Enfòmasyon Enpòtàn ladan. Avi sila a kapab genyen enfòmasyon enpòtan konsènan aplikasyon w la osa konsènan kouvètı asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék aksyon avan seten dat limit pou ka kente kouvètı asirans sante w la osa pou yo ka ede w avèk depans yo. Se dwa w pou resewa enfòmasyon sa a ak asistans nan lang ou pale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):

Hmoob (Hmong):
Tsbab tзвах xo no muaj cov ntsiab lus tseem ceeb. Tzej zaum tsab tзвах xo no muaj cov ntsiab lus tseem ceeb bxog xo dain ntwav thov kev pab los yoj koj qhov kev pab cuam los ntsawm Premera Blue Cross. Tzej zaum muaj cov hnbv tзвах ceeb usas rau havu daim ntwav no. Tzej koj kjuv yau tu uaa yam uss peb km koj uas tis pub dhaav cov caj nyong uas teev tseg rau havu daim ntwav no mas koj thaj juv yau tu baias kev pab cuam kho mob los yoj kev pab them tej nqi kho mob ntwav. Koj muaj cai kom lawv muab cov ntsiab lus no uas tuu mbu uaa koj hom lus pub dawb rau koj. Hu rau 800-722-1471 (TTY: 800-842-5357).

Iloko (Ilocano):
Daytoy a Pakdaara ket naglaion iti Napateg nga Impormasion. Daytoy a pakdaara mabalin nga adda ket naglaion iti napateg nga impormasion maiyanggep iti aplikasyonowo yeno coverage baben a Premera Blue Cross. Daytoy ket mabalin dagiti importante a pelsa iti daytoy a pakdaara. Mabalin nga adda rumbeng nga aramidenyar nga addang sakbay dagiti partikular a nalituding nga adda awid napat mapaglagulagtoy ti coverage ti salun-atyo yeno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulon o bukodyo a pagasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):
To help you, please call Premera Blue Cross at 800-722-1471 (TTY: 800-842-5357) for assistance.

Román (Romanian):

Russian (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами.
У вас есть право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que debo tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):
Ang Panawana na ito ay naglalaman ng mahalagang impormasyon. Ang panawana na ito ay maaring maari na ay magagalang ang mahalagang impormasyon tungkol sa iyong aplikasyon o pagsaskap sa pamamagitan ng Premera Blue Cross. Maaring may mga mahalagang patao dito sa panawana. Maharing mangailangan na na magsagawa ng habak sa ilang mga tawo dahil may mga tipikal na panahon unang mapanatili ang iyong pagsakop sa tulong na walang gastong mayroon ngayon. May karapatan ka na makagawa ng ganitong impormasyon at tulong sa iyong wika ng walang gastong mayroon ngayon. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้มีสาระสำคัญ ประกาศนี้มีสาระสำคัญเกี่ยวกับการขอการช่วยเหลือในการบริการสุขภาพของคุณ Premera Blue Cross และความต้องการในการให้บริการสุขภาพที่จะมีผลต่อการขยายผลของสิทธิการช่วยเหลือที่มีไว้ให้ คุณมีกฎหมายที่จะได้รับความช่วยเหลือและการช่วยเหลือในกรณีการนอนไม่ได้พัก
โทรศัพท์ 800-722-1471 (TTY: 800-842-5357).

Український (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити деякі кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

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Polskie (Polish):
To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie pozwolenia lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie prawo do bezpłatnej informacji we własnym języku. Zadzwoń pod 800-722-1471 (TTY: 800-842-5357).

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日本語 (Japanese):
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